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No. 05-380

In the Supreme Court of the United States

ALBERTO R. GONZALES, ATTORNEY GENERAL,
PETITIONER

v.

LEROY CARHART, ET AL.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

JOINT APPENDIX
(VOLUME 3)

PRISCILLA J. SMITH
Center for Reproductive Rights
120 Wall Street
New York, New York 10005
(917) 637-3600

Counsel of Record
for Respondents

PAUL D. CLEMENT
Solicitor General
Department of Justice
Washington, D.C. 20530-0001
(202) 514-2217

Counsel of Record
for Petitioner

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UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

No. C 03-4872 PJH

PLANNED PARENTHOOD FEDERATION OF AMERICA, INC. AND PLANNED PARENTHOOD GOLDEN GATE, PLAINTIFFS

v.

JOHN ASHCROFT, ATTORNEY GENERAL OF THE UNITED STATES, IN HIS OFFICIAL CAPACITY, DEFENDANT

Monday, Apr. 5, 2004

8:30 a.m.

REPORTER'S TRANSCRIPT OF PROCEEDINGS

APPEARANCES:

FOR THE PLAINTIFF:

BINGHAM MCCUTCHEON LLP
THREE EMBARCADERO CENTER
San Francisco, California 94111-4003
BY: BETH H. PARKER, Attorney at Law
DEBORAH ADLER, ESQUIRE

PLANNED PARENTHOOD FEDERATION OF AMERICA
434 W. 33rd Street
New York, New York 10001
BY: EVE C. GARTNER, ESQUIRE
DEBORAH ADLER, ESQUIRE

PLANNED PARENTHOOD FEDERATION OF AMERICA
1780 Massachusetts Avenue, N.W.
Washington, D.C. 20036
BY: HELEN T. KRASNOFF, ESQUIRE

FOR INTERVENOR PLAINTIFFS
CITY AND COUNTY OF SAN FRANCISCO:

OFFICE OF THE CITY ATTORNEY
1390 Market Street, Suite 2008
San Francsico, California 94102
BY: KATHLEEN SUZANNE MORRIS,
ALEETA MARIE VAN RUNKLE,
Deputy City Attorneys

FOR DEFENDANT:

U.S. DEPARTMENT OF JUSTICE
20 Massachusetts Avenue, N.W.
Room 7128
Washington, D.C. 20530
BY: MARK THOMAS QUINLIVAN,
W. SCOTT SIMPSON
KAIJA MARIE CLARK,
Assistant U.S. Attorneys

* * * * *

[Dr. Fredrik Francois Broekhuizen—Cross]

[492] occurs?

A. The most common circumstance would be in fetal anomaly diagnosed by ultrasound or amniocentesis. The referrals would come from maternal fetal medicine specialists or OB/GYN physicians or family physicians who practice obstetrics.

Occasionally, there are referrals from specialists in other areas, like oncologists or cardiologists. If, for instance, the diagnosis of cancer in the second-trimester is made or severe cardiovascular disease where the pregnancy would complicate the underlying preexisting internal disease. But most of the time the referral would come from the primary OB/GYN physician.

Q. And why did they make these referrals to you?

A. Currently in Wisconsin, there are only four hospitals where pregnancy terminations will take place a in hospital setting. There are probably only about four or five physicians who provide hospital-based pregnancy termination services.

And in southeastern Wisconsin, where I am located, really only one of my partners at the medical college and myself will take the majority of referrals, I guess.

At Aurora Sinai Hospital where I used to work there are occasionally other physicians provide pregnancy termination services, but they are—really do not get many referrals.

MR. SIMPSON: We will have to object to the lack of foundation for that last question and answer.

* * * * *

[494]

THE COURT: Any objection?

MR. SIMPSON: Your honor, they've included high-risk obstetrics. And Dr. Broekhuizen, as I understand, is not board certified in high-risk obstetrics.

THE COURT: Is it a requirement that he be board certified to be an expert?

MR. SIMPSON: I suppose not, your honor. We won't object to the designation as an expert, but we will be crossing on that.

THE COURT: All right. He will be accepted as an expert.

MS. GARTNER: Thank you.

BY MS. GARTNER:

Q. Dr. Broekhuizen, did you come here today to offer expert opinions regarding the partial-birth abortion ban act of 2003?

A. Yes, I did.

Q. In your opinion, could this law ban some of the abortions that you do in the second-trimester of pregnancy?

A. Yes, I think it would.

Q. In your opinion, could this law ban some of the techniques that you use to treat women who are in the midst of a second-trimester miscarriage?

A. Yes, it would.

Q. In your opinion, could this law be understood as prohibiting procedures that, in your judgment, are needed by [495] your patients due to a specific maternal health condition?

A. Yes.

MR. SIMPSON: Objection, your honor, leading.

THE COURT: All right. I allow leading questions on the background questions. And this seems to me to be still in that area.

BY MS. GARTNER:

Q. And in your opinion, Dr. Broekhuizen, could this law be understood as prohibiting procedures that, in your opinion, are needed by your patients due to a specific fetal condition?

A. Yes, they would.

Q. And could this law be understood in your opinion as prohibiting procedures that in your judgment are

needed by your patients to obtain information needed to plan for a future pregnancy?

A. Yes, they would.

Q. Dr. Broekhuizen, you've indicated that some of your patients have chosen to end their pregnancy due to a maternal health condition; is that correct?

A. That's correct.

Q. Does this sometimes arise with medical conditions that the woman had prior to becoming pregnant?

A. Yes, it would.

Q. Could you give me some examples of those?

A. It could be severe cardiopulmonary disease. What comes to [496] mind would be a condition called pulmonary hypertension where carrying a pregnancy may have a mortality risk as high as 30, 40 percent. Patients with severe coronary heart disease. Patient with end stage renal disease, liver disease.

Q. And do some of your patients choose to end a pregnancy due to a medical condition that is unrelated to the pregnancy but is newly-diagnosed during the pregnancy?

A. Yes. Examples of that would be when a new diagnosis of cancer in the second-trimester.

Q. And why would a diagnosis of cancer lead some patients to choose to end their pregnancy?

A. The treatment for the cancer certainly would interfere, could cause—or could cause birth defects or could interfere with the normal development of the pregnancy. Or the pregnancy itself, right, would make the treatment more—make the treatment more complicated or interfere with the success of the treatment.

Q. And does it sometimes happen that a pregnancy termination is indicated due to a pregnancy complication?

A. There are situations where pregnancy complication even prior to 24 weeks would be the reason for pregnancy termination. What comes to mind would be a condition called triploidy, where there is a total extra set of chromosomes that is in itself is a lethal fetal anomaly. But that is associated [497] with a placental condition and increased risk of early onset of pre-eclampsia, which is a pregnancy complication.

Q. And in your practice, in what general time frame of pregnancy are abortions for maternal health conditions performed?

A. Up till the legal limit in Wisconsin: 24 weeks.

Q. And when do these conditions tend to be diagnosed? Is there a typical time frame?

A. There is really not a typical time frame. Some of them would be fairly early terminations, because the patient is very well-aware of her serious health condition. But, for instance, in family planning, methods may fail. Those patients tend to be referred relatively early.

On the other hand, there are patients who seek or who have problems I accessing prenatal care or unaware of their own health conditions where sometimes this may be relatively late.

Q. Do your patients ever choose to end their pregnancies due to a fetal condition?

A. I would say the majority of the terminations I perform are for fetal conditions.

Q. I think you have described a few of those, but can you just briefly describe a few other conditions that you typically see in your practice where women choose to end their pregnancies for a fetal condition?

[498]

A. Well, they would range from lethal fetal anomalies, chromosomal anomalies as trisomy 13, or 18, or triploidy. Lethal anomalies that are more structural in nature like anencephaly where there is no development of the brain. Conditions as renal agenesis where there is no development of any kidneys, which then leads to nondevelopment of the fetal lungs.

And then, there are the conditions as trisomy 21 or spina bifida, which by itself are not lethal, but are diagnosed by ultrasound and amniocentesis where patients choose to have a pregnancy termination.

Q. In what general time frame of pregnancy are abortions for fetal conditions typically performed?

A. More—there has been some shift in the last 20 years. With the ability to diagnose some fetal anomalies by chorionic villus sampling or DNA analysis, at least some of the diagnosis when there is a strong family history or in high risk has been moved to be earlier part of pregnancy. But some of the structural anomalies, which I diagnose by ultrasound in patients who do not have a priority risk, tend to be more later in the pregnancy.

Q. And is it the case that all of the chromosomal anomalies tend to be detected earlier in pregnancy with chorionic villus sampling?

A. No, that very much depends on what is the practice in a [499] given community as far as prenatal

diagnosis. And it is my sense that in the Midwest where I live amniocentesis is still the number 1 diagnostic tool used by patients with advanced maternal age or an abnormal triple screen, while I think on the west and the east coast there may be more chorionic villus sampling done.

But in my environment most patients with fetal anomalies are after—are diagnosed after 16 weeks.

Q. Are there particular fetal anomalies where it is in the woman's physical health interest to end the pregnancy without carrying the pregnancy to term?

A. There are diagnoses and situations where the continuation of the pregnancy will have direct—will have direct effect on the ability to deliver vaginally.

There are conditions where macrocephaly will develop where the fetal head can become so big that it will be too big to pass through the birth canal.

There are conditions as nonimmune hydrops or fetal ascites. That means fluid gets accumulated in the fetal abdomen or edema is developing in all of the fetal tissues where part of the fetal body can become so big that it would be impossible to deliver vaginally. And I would consider those situations where that is going to develop or run a test to potential to develop, especially in the context of a lethal anomaly, a maternal indication for a pregnancy termination or [500] even earlier induction after 24 weeks to avoid surgical procedures with more morbidity and more complication.

Q. When you refer to avoiding a surgical procedure, what surgical procedure are you talking about avoiding?

A. That would be a cesarean section or a variant of cesarean section, either hysterotomy or a cesarean section.

Q. Dr. Broekhuizen, when a patient is referred to you for pregnancy termination, what is the first thing that you do?

A. Basically, in all patients I kind of collect the information that I have or I collect more information from them. And so I confirm the diagnosis. I identify the reasons why they would choose to have a pregnancy termination.

There are situations where I will ask one of my colleagues to give a second opinion about a given diagnosis. There are situations where I may do an ultrasound myself to confirm the situation.

Subsequently, I will go in detail with the patients about what therapeutic options there are. And on the more circumstances that would mean a detailed description of what a dilation and evacuation procedure would be and detailed description of what an induction method would be.

And during that detailed description I will describe the complications and risk of these procedures. I would compare that with the risk and complications of no intervention. That means continuation of the pregnancy. And [501] after that would come to a conclusion with the patients about what they would consider the best option under these circumstances.

Q. Do you ever—in the case where the indication for the termination is a fetal anomaly, do you talk with your patients about autopsy or genetic testing?

A. Yes. There are scenarios where there is—where it is clear from the ultrasound findings that there is a lethal anomaly, but, for instance, no cytogenetic testing, no chromosomal analysis has been done yet. That could be done before the procedure or as part of the procedure if amniocentesis is done.

Or it could be done on placental or fetal tissue after a delivery. And there are situations where there are lethal syndrome that there is a lot of problems. Or in the case of a lethal anomaly, a lethal syndrome, where a detailed autopsy would maybe make the diagnosis more correct or more precise.

And during this discussion, we often end up talking about:

> "Well, what information do you need for a future pregnancy?" Because the question that most patients have is:
>
> "Well, is this going to happen again? And what are my chances of that happening?"

[502]

And so there are situations where an autopsy and a detailed examination of the fetus is very important. And there are situations where that really is not that important.

In diagnosis and known chromosomal anomaly, we know what the qualities of the structural anomaly. If there is normal chromosomes, but an unusual syndrome, the precise nature of that syndrome is important to have that information to counsel the patient for a future pregnancy.

Q. And in addition to yourself, are other physicians involved in counseling and advising the patient?

A. Yes. As I said before, sometimes specialists in other areas, pulmonary specialists, cardiologists, cancer specialists already are involved and have discussed with them, you know, the risk of their medical disorder with continuation of the pregnancy.

In the area of fetal anomalies, it is not uncommon for us—for me to actually have the patients talk to pediatric neurosurgeons, any pediatric subspecialty related to the particular anomaly to have the patient be knowledgeable about what is the exact neonatal prognosis. Because in the nonlethal anomaly area, it is obviously the morbidity and how sick and the long-term prognosis of the newborns that can be deciding points in the patients to make decisions about continuation of the pregnancy or having a pregnancy termination.

[503]

At the medical college we have a program that's called "fetal concerns program," where patients are being referred in the diagnosis of the fetal anomaly. And the number 1 purpose of that program is to have babies born in hospitals where neonatal surgery can be done with the highest success rate.

So this is in the context of all anomalies, right, then one encounters a lot of noncorrectable fetal anomalies. So a program like that actually attracts a lot of tragic lethal anomalies, and those are the patients that I have to deal with then.

Q. In your practice, how is the decision made regarding what method of abortion the woman will have?

A. As I explained before, I will go in—well, I make it clear upfront that I prefer not—will do D&E's up till 20 weeks, unless there are three clearly overriding reasons that an induction would be contraindicated after 24 weeks.

Otherwise, it depends on—the patients really will make the decision about what methods she will choose. What—there are many factors that play in these decisions. Some of them are the need for an autopsy or further testing.

Other factors are the patient's personal beliefs, part of their religious belief. There are patients who really have problems with the destructive nature of a D&E procedure and prefer an intact delivery. And there are patients who have [504] strong feelings about the labor process under these circumstances, and based on their previous experience with labor may be really reluctant to undergo an induction method.

And in my opinion, the most important part is to actually ascertain their firm—their firm belief that they are doing what is best for them. And I—the best I can do is give them the risk and complications of the two procedures so they can make an informed choice that they are comfortable with, because I consider both of those methods very safe.

And my general—even while I go in detail about the complications of these procedures, I always put a surrounding comment there that continuation of the pregnancy and going through childbirth there's a possibility of cesarean section always is a higher—entails a higher risk than any of these procedures.

Q. What, specifically, do you tell your patients about the risks and potential complications of D&E and induction?

A. Well, the three—the complications that are the most relevant to the patients are damage to the cervix or the uterus, and complications as hemorrhage and infection. And they could occur, right, in both methods.

Q. I am sorry. All of those complications could—

A. All of those complications could occur with both methods. The difference—the difference between the two methods is that the—there may be subtle differences in the incidence of [505] these complications. And many—for many patients it is actually not the complication itself, but the consequences of the complications that they are interested in.

In other words, even while the best example is the perforation or damage to the uterus has the potential, even though that is very rare, to leading to a hysterectomy.

For a patient in whom this is the first pregnancy, who clearly did not ever intend to be there at this point in time, she may weigh that complication a little higher in comparing induction versus D&E procedure versus the patient who has already had several children, who is 44 years old, where that complication or the consequence of that complication, right, has less weight than in the first patient.

And so many patients in my experience ask me:

> "Well, what would happen if that complication occurs?"

And I find that more important to actually discuss through than give them just numbers and say:

> "Well, the complication rate is .3 percent for this or .2 percent for this."

Patients are really interested in what it means to them as far as their future futility or childbearing.

So that's basically what I do during this counseling.

Q. I think you indicated that there are some women for whom [506] labor induction is contraindicated; is that correct?

A. Well, there are patients who have a previous scar in their uterus from a previous c-section. And even while we are not—I don't think we really know what the exact incidence is of rupture of that scar with the induction methods—let's say between 20 and 24 weeks—ruptures clearly have been described and we know at term that that would be a risk of labor. And so I think that could be—that certainly would be a relative contraindication and something the patient needs to be aware of: that there is that risk.

Q. Other than a woman with a prior uterine scar, are there other situations in your practice where you consider induction to be contraindicated or at high risk for the woman?

A. When there is a placenta previa.

Q. Can you explain what that is?

A. Placenta previa is where the placenta is located over the cervix. And that is a situation where if labor were to occur the cervix would open, the placenta would separate, and that would lead to bleeding.

And in the situation after 24 weeks that would lead to a cesarean section. After 22 weeks, bleeding would occur under those circumstances, and then there would be more hemorrhage and more bleeding with the induction method than with the D&E procedure.

Q. And are there situations or conditions where the actual [507] not where it is not the labor process itself that is contraindicated, but where the medication used to induce the labor is contraindicated?

A. Yes, there are medications being used would be generally used for induction methods nowadays would be misoprostol. And there used to be other prostaglandins. And there are conditions where prostaglandins may have undesirable side effects in patients with certain maternal conditions like severe asthma.

Q. Dr. Broekhuizen, you talked about an uterine scar being a relative contraindication; is that correct?

A. I do not think that there ever is an absolute contraindication for any of the methods. I think there are differences that are significant for individuals, and I think a relative contraindication would be a set of patients would be need to be well-informed about what complications may arise from that particular procedure.

Q. If the woman had more than one uterine surgery would the risks of labor increase?

A. The risk of rupture would increase.

Q. In addition to D&E and induction, are there any other ways of ending a pregnancy previability in the second-trimester?

A. There would be—there would be the possibility of serial dilatation, that in itself would lea l to a dilatation wide enough that the fetas would deliver com-

pletely. Or that in [508] itself would initiate a labor process.

Q. And could you ever use a hysterotomy or a cesarean section method to end the pregnancy?

A. Well, that is clearly a possibility to do a hysterotomy or cesarean section, but given the circumstances that I prefer pregnancy termination most patients would not want to undergo a more major surgical procedure.

And so my goal is to avoid ever having to do that prior to 24 weeks. Now, I have done hysterotomies where inductions have failed, and so it's not that that is not an option, but it would be the last option.

Q. In those situations where you used a hysterotomy where induction failed, why didn't you convert to a D&E-type procedure?

A. Well, the induction failed, but then the conversion to a D&E procedure failed, as well. So, in other words, that was the next step, and then when that failed—those were two situations, two patients that I recall where they had significant cervical scarring from previous surgical procedures to their cervix. And it was just impossible to achieve sufficient dilatation or any dilatation at all.

Q. And, Dr. Broekhuizen, just to be clear, when you use the term "dilatation" does that mean the same thing as dilation?

A. That is the same term.

Q. Dr. Broekhuizen, you said that when you're in the process * * *.

* * * * *

[510] procedure you will be in the hospital for about one-and-a-half, two hours. And then, you can go home."

And then, I will give them the instructions about when I will see them back, and know what kind of precautions she has to take until I see her back.

We will discuss in the cases of the need for cytogenetic testing or that she agrees to have that done, analysis of some of the tissue.

There are even situations where patients have requested even with the D&E procedures prior to 20 weeks, even though there is no burial requirement in Wisco: sin of less than 20 weeks, but there are situations where the patient actually ask to have clergy involved and have blessing of the remains.

And I discuss that type of support with patients.

Q. Let me ask you some follow-up questions on that. You said that you would place laminaria or misoprostol or both. How—how would you make the determination of which you would—which or whether you would place both?

A. It has evolved over the years. I used to place laminaria. Then up until about—up until 18 weeks I will only use misoprostol. After—from between 18—beyond 18 weeks I will place laminaria and misoprostol, currently.

Q. And when you use the laminaria, how do you determine how much laminaria you will place in the patient?

[511]

A. I basically will place as many laminaria as I safely can place in the cervix.

Q. And when you are using the misoprostol—are you actually—you're using the misoprostol with every D&E patient now; is that—

A. I use actually misoprostol with every pregnancy termination up until 18 weeks.

Q. Okay. And then after 18—if you are doing a D&E between 18 and 20 weeks?

A. I will place laminaria plus misoprostol.

Q. How do you administer the misoprostol?

A. I place the misoprostol vaginally.

Q. And what—can you explain what misoprostol does to prepare the cervix for the evacuation?

A. Misoprostol will have a direct local effect on the cervix and softens it and dilate it, as well as have an effect on uterine activity. And it will start uterine activity that is the combination of that will lead to a soft, pliant and often dilated cervix.

Q. Can the effect of misoprostol on the cervix be predicted ahead of time?

A. No.

Q. In your practice, have you seen that some women can deliver the fetus completely simply as a result of the misoprostol that you place prior to the D&E?

[512]

A. Yes, I have seen situations where the misoprostol led to a rather rapid labor process where in the four

hours between the placement of the misoprostol and the planned D&E delivery has completely taken place. And I have encountered situation where delivery partially has taken place.

Q. In the situations where the delivery has partially taken place before she comes into the operating room, could the fetus be outside of the woman's body in part to the extent where the fetus is out of the uterus past the fetal navel?

A. That is possible, depending on the size of the fetus and the gestational age.

Q. Could the fetus be alive at that point?

A. It could be alive.

Q. And how would you complete the procedure in that circumstance?

A. By the simplest possible extraction way. It may —the cervix may be dilated sufficiently that the delivery process can be completed by just traction, and the head will follow.

More commonly, if the trunk and the extremities have delivered, the cervix may not be dilated enough for the head, and the simplest possible compression-decompression method I would use to effect delivery of the after-coming.

Q. And would that compression or decompression method result in fetal demise?

A. If the fetus will be alive at that time it certainly would.

[513]

Q. Do you advise your patients when you are describing the procedure to them that misoprostol may have this effect of resulting in either complete or partial delivery before the actual operation or surgery begins?

A. Yes, I explain to them that there are two—well, there are two purposes of placing the misoprostol. One of them would be to avoid as much as possible mechanical dilation with metal dilators.

The second purpose would be to—advantage may be that the cervix is sufficiently dilated that it will not require many instrumental passes. And to some extent if that were to happen, that would reduce the morbidity of the procedure, in my opinion.

Q. And when you are beginning the—when the fetus doesn't deliver at all because of the misoprostol so the fetus is completed in utero when you go into the operating room when you begin the evacuation part of the procedure can the fetus be alive?

A. I think if all the misoprostol has done is to achieve dilatation sufficiently for me to introduce a large suction canula or instrument, I would assume under most circumstances the fetus is still alive.

Q. And you had mentioned talking to the woman about her choices of analgesia and anesthesia. Can you explain what those—what her choices are in that respect?

[514]

A. Are you asking about the D&E?

Q. Yes. In the D&E context, yes.

A. Well, the choices would be a spinal anesthetic. The other choice would be conscious sedation where the patient doesn't get intubated but receives combinations of an analgetic medications and opiate-type drug. Sometimes that is referred to as twilight sleep.

And then, there would be general anesthesia. Now, in general one tries to avoid general anesthesia because that has been associated with more hemorrhage, less contraction of the uterus during the procedure and potentially higher risk of perforation or wrong passes.

But there are situations where very obese patients, in patients with sometimes more serious medical conditions where anesthesiologists will come to the conclusion that general anesthesia, they won't have more handle on complications that could arise during the surgery.

But the majority of procedures that I perform I know are done under general anesthesia.

Q. And Dr. Broekhuizen, when you begin the evacuation part of the procedure, what is the typical distance between the external part of the cervix and the vaginal opening? If it helps to refer to either of these charts, feel free to do so.

A. Well, it very much depends on the mobility. It depends on the individual patients. Having given birth certainly creates [515] more mobility to the cervix and to the birth canal. But basically one places an instrument. And I use a LS clamp on the anterior or posterior lip of the cervix. And I pull it down as far as possible, because one wants to have a straight passage for instruments.

And there are situations where actually patients in dorsolithotomy position, where the legs are up. One places the instrument where the cervix itself can come to the introitus. There are other situations where that would only happen halfway into the vagina. And there are fairly rarely situations where it actually may be able to be pulled outside the introitus.

Q. So that the cervix is actually out—already outside of the woman's body?

A. Correct.

Q. And do you do D&E procedures under ultrasound?

A. After 18 weeks I will always use ultrasound now. Prior to 18 weeks, not all the time.

Q. What determines—prior to 18 weeks, what determines whether you choose to use the ultrasound?

A. It's proudly my findings during the insertion of the laminaria that will help me determine. If I cannot place many laminaria, if there is something on the examination that makes me think I may have more problems identifying parts, but it is very subjective measure or a determination on my part.

Q. In performing the actual evacuation part of the procedure * * *.

* * * * *

[517] passing this law made certain factual findings?

A. I am aware of the description of factual findings. I am not sure what these findings are based on.

Q. Are you aware that one of the findings that Congress made was that converting the fetus to a breech position during an abortion procedure increases the risk

of uterine rupture, abruption, amniotic fluid embolus and trauma to the uterus?

A. I am aware that that was stated. I am at a loss to explain this in the context of a second-trimester pregnancy termination or an induction method up to 24 weeks.

I think that what's being referred to are findings and effects in the obstetrical literature if one did these procedures later in pregnancy, that that would be an association with amniotic fluid embolism and abruption.

And so I think that this applying facts and knowledge about of obstetrical practice after viability to a situation that it really should not, has no application for it, in my opinion.

Q. So, in your opinion, is there a risk of—are there any special risks to the woman of changing the lie of the fetus during a pre-viability D&E procedure?

A. I am unaware of anything in the literature about D&E procedures that has associated the procedure with any of the complications that you've just described.

Q. Isn't—

[518]

A. And so, I think the only reference that I think I found was to Williams Textbook of Obstetrics. And, specifically, I think the chapter about some are in breech presentation. And that chapter is written about the management of birth later in gestation. And it is not written on the management of pregnancy termination by induction or D&E prior to 24 weeks.

Q. Dr. Broekhuizen, when you are evacuating the uterus in a D&E procedure, what is your objective?

A. My objective is to evacuate the content of the uterus, the fetus and placenta, with the least possible trauma to the mother in the shortest period of time.

Q. And why is it important to do it in the shortest period of time?

A. Because during this procedure, inevitably bleeding will occur. And the bleeding will probably not cease until the evacuation is complete.

Q. You also said your goal evacuation or your objective is to do this with the least possible trauma to the woman. How do you accomplish that?

A. I accomplish that in three ways. The first way is to prepare the cervix prior to the procedure. And that would be the use of laminaria and misoprostol.

The second one is to ascertain at the beginning of the procedure that I have sufficient dilatation to do the procedure. And if I don't, to actually reinsert laminaria and [519] allow more time to get more dilatation so I am not trying to force instruments through insufficient dilatation.

And the third one is to make sure that I do as few passes with the instrument as possible and achieve most of the extraction part in the lower part of the uterus. And I achieve that, as well, by at sometime in the procedure giving extra oxytocic agents that actually cause more contractions during the procedure, if that is appropriate.

But the mainstay is to achieve sufficient dilatation, right, that requires easy extraction.

Q. And do you use forceps to evacuate the uterus?

A. Well, it is not forceps in the obstetrical sense. Obstetrical forceps is an instrument that one places around the fetal head to deliver the head. It is an instrument that—it is really more a grabbing instrument. There are different types. One of them is called the sopher forceps. They are kind of round. They are kind of squared, serrated surfaces that can crush tissue and hold on to tissue. And they come in different sizes.

Q. And is the purpose of using these instruments to disarticulate the fetus?

A. The main purpose of these instruments is to bring fetal parts through the cervix or fairly close to the cervix. During this process of extraction, right, disarticulation may take place, but it is not—that is not the primary purpose of the [520] instrument. The instrument is to provide traction.

Q. And is it—does it sometimes occur that disarticulation doesn't happen in the evacuation or extraction process?

A. Again, that depends on the amount of dilatation. If there is sufficient dilatation, it is possible that one will remove most of the extremities and trunk without disarticulation.

Q. Do you have a preference when you are doing the extraction whether it comes out intact or disarticulated?

A. I have to accept the situation that I encounter. But the least passes and the least disarticulation and least crushing I prefer, because that would eliminate boney fragments or sharp edges that in itself could, you

know, do damage to the cervix or uterine wall or bleeding.

Q. If disarticulation does occur, where is the part that is actually being disarticulated?

A. That could be in the uterus. It could be in the cervix. It could be—happen in the vagina—

Q. And—

A. —outside the cervix.

Q. And depending on the distance between the cervix and the introitus, could it be outside the woman's body?

A. Sure. It is possible that part of the extremity is outside the introitus when disarticulation takes place.

Q. And in circumstances where there is disarticulation, does the disarticulation occur only at the joints of the bones?

[521]

A. Not necessarily.

Q. And does it ever happen in doing a D&E that you—that you are able to bring the fetus out without any disarticulation to the point where the calvarium lodges at the cervical os?

A. Yes, that can occur.

Q. Has that happened in your practice?

A. That's happened.

Q. And could the fetus be living at that time?

A. Again, depending on the amount of dilatation and the gestational age, it could.

Q. And could the fetus at that point be outside of the introitus to the point where at least up to the fetal navel is outside the introitus?

A. Again, depending on the consensus of the cervix that could happen.

Q. In your practice, what is the earliest gestational age where you have been able to extract the fetus intact up to the point where the head lodges at the cervix?

A. I would say 12, 13 weeks. And all have and most—more often since the introduction of misoprostol.

Q. When that happens, where you are able to extract the fetus intact in that way, do you consider it to be a different procedure from an abortion in which the fetus is disarticulated before that, before that point?

A. I do not consider it fundamentally different.

[522]

Q. And you may have said this, but what determines whether you will be able to bring the fetus out intact up to that point?

A. The amount of cervical dilatation.

Q. And before beginning the D&E ask can you predict if this will occur?

A. Not really. Not when I counsel the patients. Not even when I place the laminaria or the misoprostol. I probably will have a better idea the moment I remove the laminaria and I can start the extraction method. And I am more concerned there not about having too much dilatation that total delivery could occur, I am actually more concerned about the opposite. And that

is that I have inadequate dilatation and would have to do multiple passes and lead to more complicated procedure.

So I am more looking at that point for the rare situation where I may have to, say, stop the procedure now and place some more laminaria and achieve more dilatation and bring the patient back in a few hours.

Q. In those circumstances where after you remove the laminaria or you examine the patient and you see that you have enough dilation that it is possible that you'll be able to bring the fetus out intact, would you ever attempt to disarticulate the fetus rather than attempt to extract it intact?

A. No. As I explained before, the least passes and the least—instrument passes, the easier the procedure, right? I would very much prefer that for maternal reasons.

[523]

Q. So in those circumstances where you are able to bring the fetus out intact or relatively intact to the point where the calvarium lodges at the cervix, is it usually possible to complete the delivery just with traction?

A. The fetal head is—I mean, all the gestational ages we are describing here is the largest part. And so it depends on the dilatation. There are situations where the dilatation may be sufficient enough where the head would follow, but most of the time that is not the case.

And so, then, depending on the gestational age, right, one has to decide what methods of compression and decompression will one use.

Q. And when you say "methods of compression or decompression," can you explain that a little more?

A. It's possible to grasp or to crush the skull at that time that would lead to release of brain tissue and collapse of the skull, and that in itself would do it.

It is possible that traction at the base of the skull will actually release brain fluids and brain tissue and brain fluids and make the skull collapse.

There are—not in the D&E's up until 20 weeks, but after 20 weeks there are other methods that I would utilize, especially in the case of fetal anomalies that had this disproportionally enlarged to decompress the head by placing trocars at the base of the skull and really decompress the [524] unusual content of the intracranial content.

Q. Can you describe what a trocar is?

A. A trocar is a hollow instrument with a sharp edge that one can kind of push into hole. Or at least laparoscopy surgery, which most people are aware of, one introduces those in the abdominal cavity to introduce instruments to do surgery on the internal organs. That is the type of instrument. So it is a sharp—it is kind of like—well, it's a sharp point. It is kind of like a big needle. Then, the needle is inside and whole.

Q. And how long does the evacuation part of the D&E typically take?

A. That really varies a lot. It depends. I would say that on the average that that would be 15 to 20 minutes.

Q. Does—and does the time it takes, is it affected by whether the fetus is extracted intact or whether it is disarticulated?

A. Yes. It very much depends on the amount of dilatation and the individual circumstances. And so, I am sure I've been there up to 40 minutes. And I am sure some procedures were finalized in five minutes after sufficient dilatation.

Q. Have you ever, in your practice, lacerated or perforated the cervix or uterus in the course of doing the D&E?

A. I have never perforated the uterus or had to do a laparotomy after a D&E procedure. I think on two occasions * * *.

* * * * *

[530]

THE COURT: Ms. Gartner, it is time for our first break of the morning. We will take a break now. Fifteen minutes.

THE CLERK: All rise.

(recess taken at 10:00 a.m.)

(proceedings resumed at 10:15 a.m.)

THE COURT: All right. Please continue.

BY MS. GARTNER:

Q. Dr. Broekhuizen, I think you stated that you described to the patients that you will induce the labor with medications. I am not sure you stated what those medications are.

A. Currently that would be misoprostol.

Q. And how would you administer the misoprostol?

A. Placed it vaginally.

Q. I think you said before the break that when you're describing the procedure to your patients that you tell them that you may have to convert to D&E techniques; is that what you said?

A. I think that I will counsel them on the fact that inductions sometimes fail, and then the alternative would be the conversion to a D&E method.

And there are situations where I know that spontaneous delivery will not occur because of gross disproportion. This would be usually in the case of fetal anomalies or as in high probability of not occurring, because [531] the fetal head or a part of the fetal body will be so big, in which I counsel we will start with the induction method. But we may then have to do other maneuvers to allow for—to create enough space for vaginal delivery by decompressing the fetal head or decompressing the fetal abnormal traits involved.

Q. Okay. I want to—just for now I want to leave aside those situations of the gross disproportion due to a fetal anomaly, and talk about other instances where in the inductions you switch it a D&E technique. Can you describe briefly those circumstances?

A. There are circumstances where the membranes will rupture relatively easy, early in the process, where infection may occur as a result of that. Or infection may occur even in the presence of intact membranes.

But if the mother develops amnionitis, then the time frame in which the delivery needs to be achieved, right, is clearly foreshortened, because that would represent a significant risk to the patient. And achieving, no matter what method one uses, the whole goal of that is to reduce the complications for the patients and to make it the safest procedure possible.

Under those circumstances, even patients who may—who may—really their desire would be to have an intact delivery, right, I counsel them that under those circumstances, even while that is what they would want, you know, for their [532] comfort, that under those circumstances we may have to cross the bridge to another method in order to reduce significant complications for her, and convert to a D&E procedure.

Bleeding would be another. Infection and bleeding are the two scenarios in which the timetable can become shorter. And my main goal is to have a healthy patient at the end of this procedure.

The circumstances that leads to the pregnancy terminations, in my circumstances are often already tragic. And to—no, I don't want to expose the patients to any extra risk. And that is why there need to be flexibility on their part in understanding, right, what the goal is of the procedure, and not the procedure make the goal itself.

Q. In those circumstances, for example, where in the midst of the induction the woman develops bleeding or infection to the extent that you feel that the induction—that you need to end the procedure more rapidly, could the fetus be partially delivered at that point?

A. It could.

Q. Okay. And could the fetus still be living at that point?

A. It could.

Q. When you do then convert to the D&E techniques, how would you go about completing the procedure in the circumstance where the fetus has partially

delivered but due to infection or bleeding you need to end the procedure more rapidly?

[533]

A. In the case of a partially-delivered fetus, the sufficient dilatation that I can do a compression and decompression methods to deliver the fetal head. I would, depending on the gestational age, have to choose a method that would most safely accomplish that for the patient under the particular circumstances.

Q. In those circumstances, are there options for delivering the head without using a destructive procedure?

A. Well, one option would be to continue with the induction method and wait for more dilatation, if one would not expect absolute disproportion.

But in the context of bleeding and infection, that would not be in the interest of the patient to allow more time to not effectively treat the infection.

We can give antibiotics, but best treatment of a chorioamnionitis is not only giving antibiotics, but to the evacuate the uterus as expeditiously as possible.

Q. Have you ever heard of a technique called Durhrssen's incisions?

A. Durhrssen's incisions is a technique that, again, generally it describes in obstetrical practice after 24 weeks. There the—where a baby in breech position is partially delivered, but the cervix is insufficiently dilated and the head is not too big to come to the cervix where one would place—you know, cut three incisions in the cervix to basically force the [534] cervix open and allow the head to delivery.

That is a procedure that is generally used not to —if that were to occur. It is a procedure that we all hope we never have to use, because it would be kind of like a life-saving procedure for often a premature baby in a breech presentation.

And in 2004, I think it seldom would be used because we do not delivery many breech babies—

Q. Would you—

A. —vaginally, especially not when they are premature.

Q. Would you ever consider Duhrssen's incisions to be an appropriate way in the context of an induction abortion to complete an induction where the head was trapped but the woman was infected or bleeding?

A. No, I would never consider that under these circumstances if I were to consider the consequences for the patients and future pregnancies, because that really would be purposely inflicting trauma to the cervix, which, indeed, I can repair. But that clearly could increase the risk of any cervical problems in a future pregnancy.

And in the context of a pregnancy termination, all right, one has to balance, you know, certain risks to the mother. I think that would be a risk that one would not want to expose the patient to.

Q. Are there other techniques that are used in breech [535] deliveries at term where the fetal head gets stuck to enable the head to be developed—or to be delivered?

A. There is a method. There are methods to even with breech delivery at any gestational age beyond 24 weeks, but especially at term, there are situations

where the head is deflected and there is a problem with spontaneous delivery of the head.

And there are techniques where one places a finger in the mouth or two fingers on the maxilla to actually promote flexion of the fetal head, and combine that maneuver—this is a maneuver, internal maneuver, and then have someone else push on the fetal head from just above the synthesis. Or I was actually taught to do that myself with my other hand to achieve delivery of the after-coming head.

And that, of course, is under these circumstances, a life-saving maneuver, because if part of the body is delivered and the head is still there, then we have a—there is a problem.

But that maneuver is called Mauriceau's modified maneuver. But that maneuver is really part of the obstetrical area. It is not of the techniques used for pregnancy termination less than 24 weeks for the fairly simple reason one would need sufficient dilatation for—to place someone's hand through the cervix. And that is not what was are dealing with under these circumstances most of the time.

Q. Dr. Broekhuizen, you have just been describing for us the [536] D&E and induction procedures as you do them. In your practice is there an overlap between D&E and induction abortions?

A. Well, there is an overlap in the sense that induction, right, may lead to a D&E procedure under certain circumstances. The reverse is really not true.

It is an overlap in my practice that I counsel patients on both procedures. And what is most important for me is that patients choose that procedure that they are the most comfortable with.

And so I, under rare circumstances, all right, would I exclude one procedure over the other.

Q. Dr. Broekhuizen, in your practice have there ever been special circumstances where in your opinion it was safest to do the abortion in a way where you knew you had enough dilatation that you could achieve an intact extraction of the fetus up to the head?

A. Yes, there have been.

Q. Did any of those situations involve a D&E that was performed for a serious maternal health condition?

A. Yes. One of those that comes to mind was—and the one that I actually described in detail in the Wisconsin case, was for a serious maternal condition where the goal was to do serial dilatation, avoid medication for induction and avoid the traditional D&E-type method.

Q. And can you describe the medical circumstances of that [537] woman and why you considered that to be the best method of abortion for her?

A. This was a patient who had a condition of scleroderma, who had significant pulmonary hypertension, had significant other vascular disease, who was 23 weeks and one day pregnant; was transferred from another hospital to the tertiary care institution I was working at that time. She was in the critical care unit. She was very unstable. She was on multiple medications. And it was clearly felt that the continuation of the pregnancy would be—would lead to her death.

The internal medicine specialist and the pulmonologist and the cardiologist really felt that prostaglandins were contraindicated in this patient.

Q. Let me just interrupt you there. Is misoprostol a prostaglandin?

A. Correct. Were contraindicated in her situation. She thought that the whole laboring process with fluid shifts and time would be more stressful for her than—in other words, induction was not the best option.

The option of a D&E procedure where the patient would need to have anesthesia, was already —anesthesiologists were very concerned about what anesthesia—what anesthesia method to give her. And if there was a procedure, that would have to be as short as possible with the least amount of [538] anesthesia. That was kind of the scenario we were confronted with at that time.

And I decided to proceed at that time with serial dilatation where we placed laminaria every four to six hours. And the concept was that that, in itself, may lead to sufficient dilatation that we could take the patient to the operating room with minimal medication, had sufficient dilatation that we could do at least a partial extraction or maybe a total extraction.

And that is what we set out to do under those circumstances.

Q. And what actually happened with that patient?

A. That patient we placed the laminaria three times. The last time we were up to about four or five centimeters dilatation. And when we actually took her to the operating room four hours later the fetus had completely delivered so we didn't have to—and, actually, the placenta was sitting in the cervical os. So basically we had just to grab the placenta, and the procedure completed itself.

But I would have been prepared at that time to —assuming that there would have been a partial

delivery and the head still there, to do compressing and decompressing methods.

Q. And in your practice have you treated other patients in similar situations where induction was clearly contraindicated, but this type of serial dilatation technique was in your best [539] judgment the optimal for the patient?

A. In some over 20 years, cases sometimes blur. But I think I have done at least two other cases of similar nature at less gestation age. But, again, situations where it was felt that avoiding of medication, surgery, anesthesia or minimizing that and serial dilatation would be the best method.

Q. And Dr. Broekhuizen, in your practice have there been other circumstances where your patient had compelling personal reasons for having a D&E where the fetus was removed intact and where you attempted to do that for her?

A. I had a patient that had was diagnosed with a lethal skeletal dysplasia.

Q. The fetus was?

A. The fetus had skeletal dysplasia form of dwarfism incompatible with survival. Most patients under these circumstances, after the counseling that I described before, since there quite often is a need for a more precise diagnosis and autopsy, we opt for an induction method.

This patient had a previous cesarean section and very traumatic birthing process the first time and really did not want to have an induction. Not so much because of the rupture risk, but really because of the experience of going through a laboring process.

And she, again—and at the same time she really was interested in having as much information. And so, we need [540] at least the trunk and skeletal part. That examination was important for her. And we decided to embark on the same method as I described in the previous case with serial dilatation, which could lead to laboring process, which would be maybe a little bit more or less painful or physiological or a significant dilatation that we could take the patient and do a partial or total extraction.

Q. And what happened with this patient?

A. The serial dilatation in the sense was so successful that, again, this patient delivered spontaneously. But it was very short time of labor perceived by her. So she was—it ended up exactly as what she had wanted it to be.

Q. And have you had other patients who felt strongly against induction, but who wanted an intact fetus for autopsy purposes?

A. Probably similar scenario. It is very rare, but one or two times.

Q. Okay. And I think you've alluded to this already in your testimony: have you performed induction abortions where you knew ahead of time that due to some type of gross fetal disproportion the head or another body part would become lodged at the cervix during the induction and you would have to complete the abortion instrumentally?

A. That probably has happened more often than the two previous scenarios. The case that I described in Wisconsin a case was a situation with a lethal chromosomal anomaly and significant [541] macrocephaly that clearly was incompatible with survival. But the

head was going to—had already reached proportions that were larger than the head of a baby at term, where the alternative would have been to do a surgical procedure like at that time that really would have been a scar as big as a cesarean section scar. Or an induction and being prepared to decompress the fetal head and to let the skull collapse to allow for vagina delivery.

And in the context of the lethal anomaly this patient really didn't want to expose herself to a surgical procedure except if tragic development. And the plan was to induce labor. When there is that much disproportion, it's usually in a breech presentation. And to be prepared at sufficient dilatation to be decompress the fetal skull.

Q. And what actually happened with that patient?

A. That patient actually—that went according to plan. She delivered the body partially. At that time it was sufficient dilatation that I could visualize the base of the skull and insert a thin trocar to reduce the fluid. And at that point, of course, fluid and brain tissue will appear.

I think I still needed to have some—I used actually premie-type of obstetrical forceps because I still needed to create some collapsing of the skull. But I could use that type of forceps at 6 or 7 centimeters of dilatation.

Q. Did you say the trocar when you inserted it, was that under [542] your direct visualization?

A. It was under direct visualization.

Q. And was the fetus—in that case, was the fetus alive at the point when the head lodged at the os?

A. I know in that circumstance that the cord was pulsating at that time.

Q. And have you performed other similar abortions in your career where you knew that the head or another very large fetal part would lodge without being able to complete the induction without instruments?

A. Yes. This clearly has happened more often. I had a situation like this only a few weeks ago.

Q. Dr. Broekhuizen, I want to ask you a few more questions about these patients or these scenarios you were just describing.

Before I do, let me ask you: am I right that you described these three scenarios in your declaration in this case?

A. Yes, I did.

Q. And did you discuss them in your deposition in this case?

A. I did.

Q. At the time of your deposition did you also state that there were other similar cases like them?

A. Yes, I did.

Q. At any time in this case has the government requested that [543] you produce the medical records for these abortions or for similar abortions you performed?

A. No, they have not.

Q. Dr. Broekhuizen, in your opinion were these abortions where your goal was intact extraction to the calvarium, were these the safest and best options for these patients?

A. In my opinion they were the safest from the perspective of the least maternal health risks or complications.

Q. And—

A. More importantly, these were the choices that the patients made. I have had—I have done surgical procedures on patients with lethal anomalies where patients—that was their choice.

Q. When you say "surgical procedures"?

A. Like c-section or hysterotomy. They chose not to have this procedure done.

Q. So is it the case that sometimes patients choose procedures that you know carry more health risk to them?

A. Sometimes patients choose for their personal beliefs procedures that if one were to compare one complication with another would be little higher complication than the other.

And so sometimes patients weigh the medical risk of procedures, but at the same time balance that with their personal beliefs or their personal feelings about what is acceptable to them.

[544]

I am sure that religion and religious beliefs often play a role in this, and I have no problem if patients make these informed choices to do a procedure that may have a little bit higher risk than another one, because all of these procedures, right, in itself are safe compared with many complications that patients expose themself in any pregnancy and with childbirth.

Q. In your opinion, are there any special risks to extracting the fetus intact in a D&E procedure?

A. There are no—the only difference is achieving larger amount of cervical dilatation. That is the critical difference. The—it is possible that compared to the D&E the least passive of instruments would actually reduce the risk of direct trauma to the uterus.

The only fundamental difference is if one tries to achieve more dilatation.

Q. Just to put that in context, if you are assuming, say, a 22-week D&E, what would be a typical amount of dilatation that you would get for a D&E at that gestational age?

A. I think at 22 weeks one would try to achieve 3 to 4 centimeters.

Q. What about if you were doing an induction abortion at 22 weeks, how much dilatation would there be?

A. I think probably most of the time six, seven centimeters would be sufficient for delivery.

[545]

Q. And then, just to put that in the context of vaginal delivery at term, how much dilatation would you need if a woman were delivering a baby at full term?

A. Ten centimeters.

Q. And based on your clinical experience and your reading of the medical literature, can you summarize your understanding of whether cervical dilatation using gradual osmotic dilatation or misoprostol to prepare the cervix for a second trimester D&E is associated with cervical incompetence in future pregnancies?

A. My reading of the literature is this: up to 20 weeks there is, I think, sufficient evidence to conclude that with modern methods of cervical dilatation there is no increased risk of premature delivery or cervical incompetence in subsequent pregnancy.

There may be with mechanical dilatation. And after 20 to 24 weeks, I do not think that there is sufficient evidence and sufficient literature out there to make a statement for or against. Or there is no positive nor negative to my knowledge at this particular point.

Now, I need to use that lack of information when I counsel patients. And I actually counsel patients up to 20 weeks I do not think that any of the methods that we have, hygroscopic dilators or misoprostol would pose that risk. But after 20 to 24 weeks it may be there. And I counsel them that if it is, it would be a low risk.

* * * * *

[547] treatment—sometimes diagnosis and treatment of a precancerous condition of the cervix where part of the cervix is removed with an electrical loop.

And sometimes precancer of the cervix can extend into the cervical canal, and that has to be removed pretty high up there where one could lose, let's say, half of its cervical length.

And, again, there is a concern: can that lead to weakness of the cervix in a subsequent pregnancy?

Q. When you say that you have patients that are having abortions after 20 weeks and you counsel them that:

"We don't know about the risk, but there could be a risk," do you do that for both D&E and induction abortions?

A. Yes, I do.

Q. And is this—is that, the uncertainty about that, an important consideration for your patients?

A. I don't—I cannot recall any patient for whom that ever has been the deciding reason to undergo or not undergo a pregnancy termination at that gestation rate, because the reasons for the pregnancy terminations are usually very clear to them and would override this concern.

Q. Okay. And then, just talking, again, about those three scenarios: The woman with scleroderma; the woman with the fetus with skeletal dysplasia; and the very high macrocephalic * * *.

* * * * *

[551]

Q. Could—in your opinion, could this law be understood as banning some of the D&E's that you do?

A. I am very concerned that the law would ban some of the procedures I just described.

Q. Just to follow up on Judge Hamilton's question, are you concerned about this law only in those cases where—the impact of the law only in those cases where you do the serial dilatation with the intent of getting to the point where you know you'll have enough dilation to bring the fetus out intact, or would you think it would also apply to the other D&E's where you may or may not have enough dilation to bring it out intact?

A. I think it's—my concern in both scenarios. I am concerned in the situations that I described as in the three cases where that was—the goal was to achieve partial delivery or possibly intact delivery.

But I am as well concerned about the application of this language and this procedure to any D&E procedure, where this could happen without that being the primary goal.

Q. And in your opinion could this law also be understood as banning some of the induction abortions you do?

A. It would. I would be very concerned that it would ban some of the induction methods in which I know that I have to convert to an element of—maybe not an element. Where it would include part—the situation where I can anticipate that there will be partial delivery, and I know that there is going to be [552] an interrupt body part. And it may not just only be the head. I can think of situations where there would be disproportion in the fetal abdomen that would preclude delivery that I may have to decompress.

Q. Are you concerned about the impact of this law in those situations where you described where in an induction the woman starts to bleed or become infected and you need to convert the procedure to a D&E?

A. I would be concerned for the same reasons.

Q. Dr. Broekhuizen, the definition of partial-birth abortion describes two, two scenarios in terms of the fetal presentation. It talks about delivering a living fetus until, in the case of a headfirst presentation, the entire fetal head is outside the body of the mother. That is the first scenario.

And the second scenario is in the case of a breech presentation, any part of the fetal trunk past the navel is outside the body of the mother.

Are there circumstances in your practice where you've done an induction where the fetus presents in a headfirst or breech—I am sorry—headfirst or vertex presentation. And after the fetal head is outside the body of the mother, as stated in the law, you must do a destructive act to complete the procedure?

A. Yes, I have encountered that situation. There are conditions as nonimmune hydrops or conditions where there is [553] fetal ascites where there is significant amount of fluid in the fetal abdominal cavity that would lead to the abdomen being too large. Or a cystic malformation where there's a fluid-filled area. These both are lethal conditions, and I have had to use trocar or spinal needle to decompress part of the fetal chest and abdomen where the contents—in order to achieve delivery of the remainder of the baby.

Q. And was that after the head had fully delivered through the cervix?

A. That's, in these situations, the only way that one can actually do the decompression if the head is not only delivered through the cervix. If the head was actually delivered through the introitus, because I need to have the space to reach the disproportionately large abdomen.

These are fairly rare situations, but they—these are some of the more serious, you know, disfiguring fetal anomalies that one can encounter.

Q. And you have encountered them in your practice?

A. Correct.

Q. In the abortions that you have done using serial dilatation to ensure the intact fetus, knowing that you might have to use a destructive act to deliver the head, did you deliver the fetus to that point for the purpose of performing the destructive act?

A. No. My—not for the purpose, because if there—if [554] there would have been the situation where I didn't have to do that, where the head delivered spontaneously, I certainly would have preferred that.

But in certain scenarios, it is improbable, right, that the head will deliver. So it is the disproportion—let's say I described a case where the fetus head was really very disproportionate. But at 21, 22 weeks with induction method there often is enough disproportion that at the dilatation of five, six centimeters the trunk will deliver but the head will not.

So it is—while it is not absolute disproportionately, right, there is relative disproportion.

But under those circumstances, I have seen, even with the disproportion, the spontaneous delivery. But I have seen situations where that did not occur, and then I am faced with the choice of expediting the procedure at that time or not.

And that's why I need to discuss that with the patient, that option may or that situation may arise.

Q. In your practice, do you ever bring the fetus partly but not entirely out of the uterus for the purpose of doing a destructive act?

A. Not for the purpose of doing a destructive act, but I need to be prepared to have to do a destructive act.

Q. Does your purpose in evacuating the uterus vary by whether [555] you are doing a D&E procedure or an induction procedure or the serial dilation-type procedure that you described?

A. The purpose is to evacuate the content of the uterus in the safest possible way for the patient with the least complications, regardless of what methods I would choose or regardless what method the patients would prefer I use.

Q. Okay. Dr. Broekhuizen, do you ever treat women who present to you in the midst of a spontaneous second-trimester miscarriage?

A. Sure I do.

Q. And would the treatment that you offer to those women ever be covered by this law as you understand the law?

A. I think if patients present as a spontaneous second-trimester miscarriage, if in the absence of bleeding or infection, I would probably let the process naturally take place.

But in the scenario of infection or significant bleeding, I may be confronted with the situation that would be fairly similar as if I did an induction method pregnancy termination where I have to convert to a D&E procedure for maternal health reasons because now continuation of the natural process or continuation of an induction process will take more time, and in the context of bleeding or infection may increase her health risks and would increase the morbidity.

So I can think of the scenario where I would be [556] confronted with the same dilemma that I may en-

counter in the plan's pregnancy termination by an induction method.

Q. In ending the pregnancy using D&E techniques, is it possible, then, that you would extract the fetus to the point where the fetus is outside the woman's body past the fetal navel?

A. Again, if one were to convert, one would want to extract the fetus in the most safest and most expeditious way with the least potential risk for the mother. And then, since it is the extraction portion that would be the least risky part, right, one could encounter that same situation.

MS. GARTNER: Your honor, may I approach to put up the other part?

THE COURT: Yes.

BY MS. GARTNER:

Q. Dr. Broekhuizen, this is the beginning operative section of the statute. The second sentence of this subsection, which is section 1531(a), includes what is called "the life exception" to this law. If you could read that second sentence?

A. "this subsection does not apply to a partial-birth abortion

> that is necessary to save the life of a mother whose life is endangered by a physical disorder, physical illness or physical injury, including a life-endangering physical condition caused by or arising from the pregnancy itself."

* * * * *

[566] sit for the Boards.

And I couldn't because I never finished my fellowship.

Q. Doctor, you have also never had any legal training, correct?

A. No.

Q. That's corret?

A. That's correct.

Q. Doctor, in performing a D&E you reach for whatever fetal part presents at the internal os, correct?

A. That's true most of the time. I grab for the part that I can grab. Usually that's a part that is close to the internal os, but not always.

Q. And, in general, you reach for whatever part presents at the internal os?

A. I grasp for whatever part I can grasp, and that is almost never the fetal head.

Q. You generally reach for whatever part presents at the internal os?

A. Correct.

Q. Now, doctor, a mid-trimester D&E normally involves the fetus in parts, correct? A mid-trimester D&E normally involves the fetus in parts?

A. No, that's—well, that is—in the majority of cases that will take place. That will occur.

* * * * *

[584]

A. Yes.

Q. Was anything done in those instances, doctor, to improve the appearance of the fetus' head after decompression?

A. Yes.

Q. What was done?

A. The fetus was—just like a newborn—it was dressed and kind of had a little hat placed on it so that only the face was visible.

Q. So are you saying, doctor, that the evidence of the decompression of the head did not appear on the face?

A. Correct.

Q. Now, doctor, this procedure that you sometimes choose to do in which you purposely deliver the fetus intact up to the head, that is a new procedure, correct?

A. Not for me.

Q. Are you familiar, doctor, in the medical literature with references to what is sometimes called "intact D&E," sometimes called "intact D&X"?

A. I am familiar with the literature and the terminology.

Q. And that is a new procedure?

A. It is described. I don't know. It is not a new procedure in my practice. I have had to deal with situations in my practice in Africa in the '70's. And I have had to deal with fetal anomalies in the early '80's, that are similar to the situations that I described. And I have used very similar [585] methods and parts of techniques, albeit different medications and different instrumentation. And so conceptually for me this is not new.

What is new is the fact that it was kind of described as new or different from the destructive D&E procedure by other people who described it.

Q. Doctor, during your deposition did I show you a copy of a presentation by a Dr. Martin Haskell on what he called:

"Dilation and extraction," or "D&X"?

A. You showed me.

Q. Did I also show you a statement by the American College of Obstetricians and Gynecologists regarding what that statement called "intact dilatation and extraction"?

A. You did.

Q. The American College of Obstetrics and Gynecologists is also known by the acronym "ACOG," correct?

A. That's correct.

Q. If I could refer you to your deposition, please, doctor. Page 161.

Page 161, if you could read to yourself, please, doctor, lines one through 17.

THE COURT: Is there a question pending? I am sorry. Is there a question pending that you are using this to impeach him with?

MR. SIMPSON: Yes. The question is:

* * * * *

[615] evidence there to state that that is not a message for dilatation in every case, and I think I testified that I am not sure for both methods, induction or D&E procedures, that that is true after—between 20 and 24

weeks. And therefore I counsel patients on the possibility of cervical incompetence and subsequent pregnancy.

Q. Now, doctor, when you employ serial use of osmotic dilators, you put a greater number of dilators into the cervix each time, correct?

A. That's correct.

Q. You have put as many as 20 or 25 dilators into a woman's cervix at one time.

A. That's correct.

Q. Doctor, if one wanted to study whether the cervical dilatation needed for an induced abortion increases the risk of cervical incompetence in pre-term labor, you would have to follow a group of women who had undergone an induced abortion, you would have to follow them into a subsequent pregnancy, correct?

A. That would be—you would have to follow their —into a next pregnancy.

Q. And the larger that group of women the more reliable that study would be?

A. That's true. I think probably impossible to ever conduct a study of that kind.

* * * * *

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW YORK

No. 03 Civ. 8695 (RCC)

NATIONAL ABORTION FEDERATION, MARK I. EVANS, M.D., CAROLINE WESTHOFF, MD, MSC; CASSING HAMMOND, MD, MARK HELLER, MD, TIMOTHY R.B. JOHNSON, MD, STEPHEN CHASEN, MD, GERSON WEISS, MD, ON BEHALF OF THEMSELVES AND THEIR PATIENTS, PLAINTIFFS

v.

JOHN ASHCROFT, IN HIS OFFICIAL CAPACITY AS ATTORNEY GENERAL OF THE UNITED STATES, ALONG WITH HIS OFFICERS, AGENTS SERVANT, AND EMPLOYEES, AND SUCCESSORS IN OFFICE, DEFENDANT

Apr. 8, 2004
9:40 a.m.

TRANSCRIPT OF TRIAL PROCEEDINGS, BEFORE THE HONORABLE RICHARD CONWAY CASEY, UNITED STATES DISTRICT JUDGE

APPEARANCES:

FOR THE PLAINTIFFS:

AMERICAN CIVIL LIBERTIES UNION FOUNDATION
125 Broad Street, 18th Floor
New York, New York 10004-2400
(212) 549-2600

WILMER CUTLER PICKERING LLP
2445 M Street, N.W.
Washington, D.C. 20037-1420
(202) 663-6235
BY: A. STEPHEN HUT, JR.
AMY KREIGER WIGMORE
KIMBERLY A. PARKER
LORIE CHAITEN

FOR DEFENDANTS:

ELIZABETH WOLSTEIN, ESQ.
SHEILA M. GOWAN, ESQ.
SEAN LANE
JOSEPH PANTOJA
U.S. Department of Justice
86 Chambers Street, 3rd Floor
New York, New York 10007
(212) 637-2800

* * * * *

[Dr. Stephen T. Chasen—Direct]

[1540]

THE COURT: That's it?

MS. CHAITEN: That's it.

THE COURT: That completes that witness. Mr. Hut, call your next witness.

MR. HUT: Plaintiffs call Dr. Stephen T. Chasen.

STEPHEN T. CHASEN, called as a witness by the plaintiffs, having been duly sworn, testified as follows:

THE CLERK: Please state and spell your full name slowly for the record.

THE WITNESS: First name Stephen, S-T-E-P-H-E-N. Middle name Todd, T-O-D-D. Last name Chasen, C-H-A-S-E-N.

THE CLERK: Thank you. Please be seated.

DIRECT EXAMINATION

BY MR. HUT:

Q. Good morning, Dr. Chasen. Are you a physician?

A. Yes, I am.

Q. Are you a plaintiff in this lawsuit?

A. Yes, I am.

Q. Where are you currently employed, Dr. Chasen?

A. I am employed by the Weill Medical College of Cornell University, where I am a member of the full-time faculty.

Q. Do you have privileges, Dr. Chasen, at any hospital?

A. I have privileges to practice medicine at the New York Presbyterian Hospital and at Flushing Hospital Medical Center * * *.

* * * * *

[1551]

A. The most common context is in the second trimester for genetic diagnosis, and then it is performed typically from 15 to 20 weeks, although there are circumstances when the need for the option for that procedure arises later in pregnancy.

Q. Once the sample is taken from the amniotic fluid, is there some time required for it to be analyzed in the laboratory?

A. Yes. The most common test that is performed is a genetic test looking at the number of chromosomes, and it is done to identify fetuses that have conditions such as Down syndrome or Turner syndrome or other syndromes. That takes between one and two weeks, depending on the lab that the fluid is sent to.

Q. Do you perform surgery, Dr. Chasen?

A. Yes, I do.

Q. What types do you perform?

A. Surgical procedures. I perform Cesarean delivery, which is when a baby is delivered through an incision in the uterus and the maternal abdomen. I perform procedures in women who are pregnant, and these include something called a cervical cerclage, which is a stitch tied around the cervix. This is done with the intent of preventing preterm birth. And in some women I also perform abortions.

Q. Approximately how many times in your career have you performed abortions?

A. In my career, probably, including first and second trimester, I would estimate about 500.

[1552]

Q. How does that divide as between first and second trimester?

A. I think the first trimester abortions, and most of these I did during my residency, were probably 50 percent of it, and the rest would be second trimester.

Does the number you just supplied include surgical treatment or management of spontaneous abortion?

A. Yes, it does include that.

Q. Approximately how many abortions have you performed or supervised over the past year, Dr. Chasen?

A. About 50.

Q. How many of those were second trimester?

A. Over the last year, all of them.

Q. What type of abortions have you performed?

A. I have performed abortions using suction curettage. Typically, these are before 14 weeks of gestation. And I perform surgical abortion with dilation and evacuation in which the cervix, unless it is a woman that has a form of preterm labor miscarriage who spontaneously dilates her cervix.

Dilation and evacuation involves placing laminaria in the cervix and then evacuating the fetus and the placenta from the cervix one or two days later typically.

Q. Have you performed second trimester induction abortions, Doctor?

A. I have, yes.

Q. You testified about your abortion procedures performed over [1553] the past year. Currently, what type of abortion procedures are you performing?

A. Surgical abortions.

Q. Are those second trimester abortions?

A. Yes. Over the last year, D&E is the only procedure I have done over the last year.

Q. Give us the range with respect to gestational age of the area in which and the time in which you performed second trimester surgical abortions.

A. With the exception of cases of fetal demise, which may exceed 24 weeks, these are all from 13 weeks to 23 weeks and 6 days.

Q. When you say with the exception of fetal demise, do you refer to situations in which there has been fetal demise prior to the performance of any surgical procedure?

A. Yes, spontaneous fetal demise or what some would call stillbirth.

Q. Did you have any training in abortion procedure or practice, Dr. Chasen?

A. Yes, I did.

Q. Can you describe that training for us, please.

A. During my residency I was trained in techniques of first trimester abortion going up to about 12 weeks and using suction curettage, which is a form akin to vacuum aspiration. That was during my residency. I had very minimal exposure and just * * *.

* * * * *

[1556] commonly on a daily basis.

Q. In the course of your clinical work, Dr. Chasen, do you have any responsibility for training other physicians?

A. Yes, I do.

Q. Could you describe that, please.

A. Sure. My responsibilities include training residents who are in training in obstetrics and gynecology and training people who have completed a residency and are doing a fellowship in the subspecialty of

maternal fetal medicine. I teach medical students as well.

Q. Does your institution, Dr. Chasen, offer any training in abortion procedures?

A. Yes, it does.

Q. What types of abortion procedures are taught at your institution?

A. Surgical abortion done in both the first and second trimester, as well as methods of medical abortion again in the first and in the second trimester.

Q. Is the intact D&E variation taught in your institution?

A. Yes, it is.

Q. To approximately how many medical students or residents?

A. All the residents have the opportunity to participate in D&E, including the intact variations, and in my residency program the majority of them do. So the majority do have exposure and do receive teaching of this.

[1557]

THE COURT: Are they required to?

THE WITNESS: They are not required to, no.

Q. How many are in the residency program?

A. There are 25 residents at any given time.

Q. Are you a member, Dr. Chasen, of any professional associations?

A. I am a member of ACOG, the American College of Obstetrics and Gynecology, and a fellow of the Society for Maternal Fetal Medicine.

Q. Have you authored any publications, Dr. Chasen?

A. Yes, I have.

Q. On what general subjects?

A. Subjects pertaining to maternal fetal medicine, some papers relating to maternal complications in pregnancy, some papers relating to prenatal diagnosis of various conditions, and a couple of papers relating to abortion.

Q. How many papers have you authored that have been published in peer-reviewed journals?

A. Between 25 and 30.

Q. What was the publication date, Dr. Chasen, of the most recent article that you authored or to which you contributed that has appeared in a peer-reviewed journal?

A. March of 2004.

Q. In what journal did the article appear?

A. That was the American Journal of Obstetrics and Gynecology.

[1558]

Q. On a generalized level, without any technicalities, what was the subject of the article in the American Journal?

A. The subject of the article was relating to first trimester screening for Down syndrome and the impact

that the screening has had on ways in which women make decisions about prenatal diagnosis.

Q. Do you yourself perform peer review for scholarly journals?

A. Yes, I do.

Q. Which ones, Dr. Chasen?

A. I have been a peer reviewer for the journal we just mentioned, the American Journal of Obstetrics and Gynecology.

THE COURT: Is that published by ACOG?

THE WITNESS: No, it is not.

A. But I have been a peer reviewer for the journal that is published by ACOG, which is called just Obstetrics and Gynecology. And I have been a peer reviewer for I believe the American Journal of Perinatology, the International Journal of Gynecology and Obstetrics, the Journal of Maternal Fetal Medicine, and I think the American Journal of Medical Genetics, I believe.

Q. Dr. Chasen, have you received any honors or awards for teaching?

A. Yes, I have. Every year the graduating chief residents in obstetrics and gynecology give an award to the one faculty member for outstanding teaching, and I have received this award [1559] three times: In 1998, 2001, and 2003.

MR. HUT: Your Honor, may I approach with exhibits for the witness, please?

THE COURT: Surely.

Q. Dr. Chasen, please have a look at what has been marked Plaintiffs' Trial Exhibit 84, tab 84 in the book I just handed to you. Do you recognize it?

A. Yes, I do.

Q. What is it?

A. This is a biographical sketch in the National Institutes of Health format. It is a curriculum vitae, or a CV.

Q. As of the date of its preparation is it an accurate summary of your education and experience?

A. Yes, it is.

MR. HUT: Your Honor, plaintiffs move into evidence Plaintiffs' Trial Exhibit 84.

MS. GOWAN: No objection, your Honor.

THE COURT: It will be received.

(Plaintiff's Exhibit 84 received in evidence)

Q. Dr. Chasen, what, if any, steps do you take to remain current on developments within your medical specialties?

A. On a monthly basis, which is the frequency of publications in those journals, I am aware of and I read the articles pertinent to maternal fetal medicine. I attend every year the annual Society for Maternal Fetal Medicine conference at which [1560] new and important research is presented. I read textbooks and newer editions of textbooks, ones that I contributed to and ones that I haven't.

MR. HUT: Your Honor, at this time plaintiffs offer Dr. Chasen as an expert in obstetrics and gynecology, in maternal fetal medicine, in abortion procedure

and practice pursuant to Rule 702 of the Federal Rules of Evidence.

MS. GOWAN: No objection, your Honor.

THE COURT: The Court will so recognize him.

Q. Dr. Chasen, in your opinion, what is the relationship between an intact D&E and a dismemberment D&E?

MS. GOWAN: Objection to the form of the question.

THE COURT: Could I have the question, please.

(Question read)

THE COURT: Sustained. Could you rephrase it, Mr. Hut.

Q. What is the relationship, Doctor, if any, between intact D&E and the dismemberment form of D&E?

MS. GOWAN: Objection, your Honor.

THE COURT: I will allow it.

A. They are both dilation and evacuation procedures in which the cervix is in most cases deliberately dilated and the evacuation component is removal of the fetus and the placenta. They are both variations of D&E, one that involves dismemberment of the fetus with forceps and the other that [1561] accomplishes D&E primarily through breech extraction.

Q. Which is which?

A. The intact version of dilation and evacuation is the one that typically involves breech extraction.

Q. What is your goal or objective when you perform an intact D&E, Doctor?

A. My goal when I perform any D&E is to do it to minimize the risk of trauma to maternal tissues, including the uterus and the cervix. In any D&E I perform, my goal is to remove the fetus as intact as possible. So my goal in intact D&E is just that.

Q. Dr. Chasen, do you prepare a patient differently for one variation of D&E versus the other at the same gestational age?

A. No.

Q. Can you describe briefly for us, Doctor, how you perform the D&E procedure in your practice.

A. The dilation portion of the procedure—again, there are some patients who have spontaneous dilation who may have been in preterm labor in whom the dilation portion is not required. But absent that, the first step in the procedure, after obtaining informed consent and having a detailed discussion with the patient—

THE COURT: I would like you to stop there, Doctor. What do you mean by detailed information with the patient?

THE WITNESS: What I mean is discussing what the * * *.

* * * * *

[1571] the heart. The most common way to do this is by injecting a needle directly into the heart of the fetus under ultrasound guidance.

In these cases the mothers are not anesthetized and the fetuses don't receive any anesthesia by route of the mother.

And in every one of these cases, upon contact of the needle with the fetal chest, I see a withdrawal response of the fetus, recoiling that I can see on the ultrasound.

THE COURT: Are you trained in fetal pain, as such?

THE WITNESS: No.

THE COURT: Next question.

A. I was—

Q. I think describing your practice in performing D&E, perhaps you want to continue that from, perhaps, from the outset.

A. Okay. My practice in performing D&E?

Q. Yes. Just describe for us, if you can, how you perform a D&E.

A. I perform a D&E, again in patients that don't have spontaneous cervical dilation.

Following the detailed informed consent process, the next step is to insert laminaria into the cervix which will accomplish dilation in advance of evacuation of the fetus and [1572] the placenta.

Depending on the gestational age and the fetal size I may put in the laminaria, may be done just one day prior to the procedure, or they may be done both two days and one day prior to the procedure to achieve a greater degree of cervical dilation.

The day after the last insertion of laminaria the patients come to the operating room, they receive anesthesia, they are placed up in stirrups, the laminaria are removed, they receive sterile wash and sterile drapes are placed.

Once they're under anesthesia I do an examination and, based on the dilation of the cervix, based on the proximity of the cervix to the opening of the vagina, based on the fetal position that I can determine by palpation or with ultrasound that I have there, I determine the, what I feel will be the most appropriate way to evacuate the fetus from the uterus.

Q. And what might those appropriate ways be?

A. The two ways to do D&E are with forceps.

And when forceps are involved, in most cases disarticulation or dismemberment of the fetus will occur in the process of removing the fetus from the uterus although, in some cases, the fetus may come out intact using forceps or intact at least to the level of the head. But, in some cases, intact entirely.

If I make the determination that the cervical dilation [1573] and the proximity of the cervix to the vagina and the fetal position would enable me to do a breech extraction, then I will deliver the fetus like that and this will involve either manually, with my hands, bringing one or both of the legs through the cervix into the vagina, proceeding with a breech extraction.

And, in most cases, the degree of cervical dilation will not accommodate passage of the fetal head through the cervix. And in this case my practice is to make an incision at the base of the skull with the scissors, which I can do really under direct visualization, place a suction device within the skull, the brain tissue is aspirated and, typically, the head then delivers easily.

Q. And what do you do in the event that you are not able to—

THE COURT: Excuse me. Does that mean because the skull collapsed?

THE WITNESS: Yes.

THE COURT: That it delivers easily?

THE WITNESS: Once the skull has collapsed.

THE COURT: Okay. Go ahead, Mr. Hut.

BY MR. HUT:

Q. When you are not able to achieve a breech extraction and a relatively intact extraction, how do you evacuate the uterus in a D&E?

[1574]

A. Again, in most cases this requires multiple insertion of forceps which will grasp parts of the fetus and in most, but not all cases, involve dismemberment of the fetus and removal from the uterus in parts.

Q. And at what point in the process, just to be clear, do you decide which variation to perform?

A. At the—after the mother is under—after the laminaria is removed the mother is under anesthesia and I do an examination under anesthesia and, again, assess the degree of cervical dilation, the proximity of the cervix to the vagina and the position of the fetus by palpation or ultrasound.

I make a general determination.

Now, in some cases I don't think I can remove the fetus with breech extraction, however, my first pass with forceps I may in fact bring a leg through the cervix into the vagina and not disarticulate or separate it from the body of the fetus.

THE COURT: Tear it off, right, Doctor?

THE WITNESS: I don't tear it off.

If that's the case then I can attempt to continue the case as a breech extraction.

Q. At what gestational age or ages are you typically able to achieve breech extraction relatively intact?

A. In general but not exclusively after about—after 20 weeks. 20 weeks and zero days there is—it's possible to do [1575] it.

At those gestational ages it is typically easier to achieve a higher degree of cervical dilation and the fetus is less likely to be dismembered or torn apart just by manual traction and doing a breech delivery.

But there have been cases of women who have had advanced degrees of cervical dilation prior to 20 weeks in which intact delivery is possible.

Q. When you perform a D&E, Dr. Chasen, where is the cervical os or opening in relation to the vaginal opening?

A. It can vary widely between patients.

In women—there are a couple factors.

Women that have been through labor before and delivered vaginally tend to have—the muscles in the pelvis are stretched and these are the muscles that support the uterus and cervix and they can have a form of condition called prolapse, which is basically when the cervix, which is usually 8 to 10 centimeters internal to the opening of the vagina, but in some women with this condition the cervix can be within a centimeter or two, can be, or visible entirely at the opening of the vagina.

Women who have the procedure under general anesthesia, the cervix is more likely to be lower because

general anesthesia provides a great deal of relaxation to these muscles that support the uterus and the cervix.

[1576] So, it depends mostly on obstetric history and it depends on what type of anesthesia is being used.

Q. And do those variables that turn on obstetric history dictate the same result in the case of a dismemberment D&E and intact D&E as to where the cervical opening is, vis-à-vis the vagina?

A. No.

In women, again, that have had one or more vaginal births before the cervix will more likely be close to the vaginal opening compared to women who haven't been through labor.

Q. And as between variations of D&E, does that affect where the cervical opening is, vis-à-vis the vaginal opening?

A. No, it does not.

Q. And in those cases where the cervical opening is at the level of the vaginal opening, where is the fetus when you extract it from the uterus in relation to the woman's body?

A. This is in D&E with intact extraction or with—

Q. Either.

As you are extracting the fetus either intact or in parts, in the case of the situations you described where the cervical opening is level with the vaginal opening, where is the fetus, either intact or in parts, as to the woman's body?

MS. GOWAN: Objection. Compound.

THE COURT: Sustained.

[1577]

MR. HUT: I will try to rephrase it.

Q. In the circumstance you described where the cervical os is at the same level as the vaginal opening, when some or all of the fetus is extracted in a D&E procedure, where is the fetus or fetal parts in relation to the woman's body?

THE COURT: Could you read that question, again? I think you have not achieved your goal in rephrasing it, but. Read the question, please?

(Record read)

THE COURT: Simplicity helps a lot, Mr. Hut. Why don't you try again.

MR. HUT: This concept is not as simple as I would like it, your Honor, and I understand the question was complex. I will try to rephrase it one more time.

THE COURT: If you take it in pieces instead of trying to do it all. Sort of like, would you give me the answer I would like, the better one I ask you.

MR. HUT: It was not my intention to ask it that way, your Honor.

BY MR. HUT:

Q. In the case of where the cervical os is at the level of the vaginal opening, where is the fetus in relation to the woman's body when extracted from the uterus?

A. Parts of the fetus may be in the cervix, in the uterus, and parts of the fetus may be external to the vaginal opening.

* * * * *

[1582] appropriate for them.

THE COURT: And you don't urge them to do one or the other?

THE WITNESS: I don't urge them to terminate the pregnancy and I don't urge them to undergo D&E.

THE COURT: Next question.

Q. In your experience, Dr. Chasen, as between D&E and induction, which form of procedure involves the most psychological stress for your patients?

MS. GOWAN: Objection.

THE COURT: Sustained. I don't think the doctor has been qualified as an expert in psychiatry, so.

Next question.

Q. In your experience, Dr. Chasen, have you seen women for who inductions are contraindicated or relatively contraindicated?

A. Yes, I have.

Q. What types of patients have you treated that had contraindications or relative contraindications for induction, Dr. Chasen?

A. Women that have scars on their uterus—whether that's from having a prior c-section or having a procedure called a myomectomy where a benign tumor is removed from the muscle of the uterus they are particularly prone to have rupture of the uterus at the site of the scar which is weaker than normal, the normal muscle of uterus.

[1583]

These women—these women, the labor process, whether it is at term for a viable baby or whether it's a

medical abortion, these women are at high risk of rupturing the uterus, particularly if they have had a version of c-section with a vertical incision, often referred to as a classical incision.

But all women with any type of c-section, even the common type, are even at higher risk.

These women—

THE COURT: Do abortions leave any scarring, Doctor?

THE WITNESS: They don't leave any scarring in the muscle of the uterus predisposing to rupture in a future pregnancy.

THE COURT: It doesn't?

THE WITNESS: It does not.

THE COURT: No matter what form that's used?

THE WITNESS: It does not.

THE COURT: Okay.

Next question.

Q. With respect to women who have had prior c-sections or myomectomies and, thus, uterine scarring, why are inductions contraindicated in this circumstance?

A. The process of induction involves pharmacologically inducing the muscle of the uterus to contract and often contract strongly.

Inducing muscle to contract that has a scar within it [1584] is a risk factor for rupture of the uterus. In the process of D&E we do not use this type of stimulation to the muscle of the uterus and the risk of rupture at the scar is lower.

Q. If the uterus were to rupture in the event of an induction abortion, would that leave scarring, assuming it were safely repaired?

A. Yes, it would.

Q. In your experience, Dr. Chasen, how common is a classical caesarean section?

A. As a percentage of all caesarean sections performed, it's relatively uncommon, probably comprising in my hospital—fewer than five percent of the cases are with a classical incision in the uterus, the type that is particularly prone to rupture in the future.

As an absolute number, we have 6,000 deliveries a year in my hospital, about one third of them are by c-section. So if there are 2,000 c-sections there may be between 50 and 100 women who undergo c-section with a classical incision.

Q. Is that each year?

A. That's each year.

Q. And approximately—withdrawn.

Would D&E present the same concern that uterine rupture for a woman with a classical c-section scar or scarring from myomectomy would?

A. D&E would not expose the patient to that degree of risk.

[1585]

Q. Why not, Dr. Chasen?

A. The risk relates to contractions in the muscle of the uterus and D&E is, involves mechanical—involves dilation of the cervix through laminaria, not through inducing contractions in the uterus.

Removing the fetus through whichever technique of D&E does not involve expulsion with contractions of the uterus, thus it avoids the stimulation of the muscle of the uterus which is what precedes uterine rupture.

Q. Do you see patients, Dr. Chasen, with cardiac disease?

A. I do.

Q. When has the indication of cardiac disease manifested in the patients that you see. And if it varies, please so state?

MS. GOWAN: Objection, your Honor. Broad.

THE COURT: Let me hear the question.

MR. HUT: I will rephrase it, your Honor.

Q. In the patients that you see with cardiac disease, can you share with the Court when the indications of that disease manifest?

THE COURT: Could you read that question to me?

(Record read)

MS. GOWAN: Same objection, your Honor.

THE COURT: I think it's unintelligible. Sustained.

Q. Describe the range of patients that you see, Doctor, with cardiac disease.

[1586]

A. Patients with cardiac disease could have longstanding disease—

THE COURT: And short duration disease, is that correct?

THE WITNESS: That is correct.

There are patients that may have preexisting cardiac disease and may not have had symptoms and may not have had it diagnosed through pregnancy but manifest through the physiologic changes in pregnancy.

And as the physiologic changes in pregnancy become more announced with advancing gestation, there are some women that may not become symptomatic until the second or third trimester of pregnancy.

Q. As between induction and D&E, Dr. Chasen, what abortion procedure would you recommend for women that you see with cardiac disease?

A. I would recommend that these women who are going to undergo abortion with cardiac disease have a D&E.

Q. And why is that?

THE COURT: Does it vary with degree with the seriousness of their heart condition?

THE WITNESS: Yes, it does.

THE COURT: I thought it might.

Q. Can you further amplify that answer, Dr. Chasen?

A. Women with—my recommendation would become firmer with [1587] more, with increased severity of disease.

Q. That recommendation would be for what, Doctor?

A. For D&E.

Q. Dr. Chasen, are you aware of other complications of induction that you have not identified?

A. Yes, I am.

One complication is unsuccessful medical induction whereby women may have a prolonged—there may be a prolonged attempt at induction of labor but some women will not expel the fetus in this process and then these women may have to undergo surgical abortion.

Q. What surgical abortion would be performed in this instance, Dr. Chasen?

A. Hopefully D&E would be available. If it's not, then hysterotomy may be required.

Q. Is retained placenta a complication of induction, Dr. Chasen?

A. Yes, it is.

Q. In your experience, Dr. Chasen, are there ever cases in which, to your knowledge, the fetus dies during the course of an induction abortion?

A. Yes.

Q. How does that happen, in your experience?

A. In inducing labor the uterus contracts forcefully, in some cases very forceful contractions can force expression of the * * *.

* * * * *

[1589]

Q. What is your opinion, Doctor?

A. My opinion is that in patients in whom I am able to do a D&E with intact extraction, that this procedure —this variation of D&E offers safety advantages compared to dismemberment.

Q. Is the intact variation of D&E, to your understanding, Dr. Chasen, recognized in any medical texts?

A. Yes.

MS. GOWAN: Object to the form of the question. In what way?

MR. HUT: I'm happy to rephrase.

Q. Is intact D&E identified as an available method of abortion in the second trimester in any medical texts of which you are aware, Doctor?

A. Yes.

Q. Which one or ones?

A. Williams' obstetrics.

Q. Do you use Williams' obstetrics in your practice?

A. Yes, I do. It's regarded as an authoritative text of obstetrics.

Q. Do you use it at Weill?

A. Yes.

Q. Does the Williams text state whether the intact D&E is favored or unfavored in any way?

A. It does not characterize it as that.

[1590]

Q. Doctor, returning to your opinion concerning the safety of intact D&E, why can intact D&E be the safest way to perform a D&E?

A. Based on my experience, complications of D&E relate to insertion of instruments, typically forceps into the uterine cavity.

Insertion of forceps in the course of dismembering the fetus and removing it, every time the forcep

clasps around some tissue, even under ultrasound guidance, I can't be certain that it's not grasping maternal tissue, the uterine wall.

So, use of forceps, and again these are used extensively in dismemberment, would increase the risk of uterine perforation.

In D&E using disarticulation or dismemberment, portions of the fetal skeleton are exposed and they may be sharp edges and removing these through the cervix may expose the cervix to trauma.

The intact extraction variation of D&E is typically, can be performed more quickly and, in my experience, with less blood loss.

Q. As between intact D&E and dismemberment D&E which, if either, poses a greater risk of retained fetal tissue?

A. Using D&E with dismemberment poses a greater risk of retained fetal tissue.

Q. Can you describe, briefly for the Court, Doctor, what, if [1591] any, health risks may be associated with uterine perforation?

A. Uterine perforation can cause hemorrhage. It can certainly cause infection. If the perforation is not recognized and the forceps pass through the perforation, then bowel or bladder can be injured. And there is a risk of death.

THE COURT: Have you ever perforated the uterus doing a D&E?

THE WITNESS: Yes, I have.

THE COURT: Have you ever been sued for malpractice?

THE WITNESS: Yes, I have.

THE COURT: Next question.

BY MR. HUT:

Q. Were you sued for malpractice in connection with the uterine perforation for which you just testified?

A. In one case involving uterine perforation I was sued for malpractice.

Q. Did the quality assurance committee at the hospital in question make any investigation or assessment of your conduct in connection with that perforation?

MS. GOWAN: Object to the form of the question. Leading.

THE COURT: I will allow it.

THE WITNESS: The quality assurance committee reviewed it and characterized it as a statistically occurring event with no deviation in medical care.

[1592]

THE COURT: Did the plaintiff recover?

THE WITNESS: Yes.

THE COURT: Next question. Have you been sued more than once for malpractice?

THE WITNESS: I was sued in that case and I was in a case when I was a resident, so that's twice.

THE COURT: Next question, Mr. Hut.

BY MR. HUT:

Q. What causes the presence of bony fetal parts about which you testified earlier?

A. Fetal dismemberment with forceps would cause exposure of bony fetal parts.

Q. Do bony fetal parts present any risk of cervical laceration, in your opinion?

A. In my opinion they do.

Q. What, if any health risks are associated with retained fetal tissue?

A. Retained fetal tissue can interfere with the process known as involution of the uterus where the uterus shrinks down to a non-pregnant size. Failure of the uterus to do this because of retained tissue is a risk factor for hemorrhage.

It's a risk factor for infection, both in the short-term, in the long-term if retained fetal tissue, especially if it causes infection, could cause scarring of the uterine cavity which could be associated with future problems [1593] in fertility or obstetric complications.

Q. Why does intact D&E reduce the risk of retained fetal tissue, Dr. Chasen?

A. In delivering the fetus intact to the level of the head and then in suctioning out the brain tissue through a small incision at the base of the skull and then removing the fetus, I can clearly identify that all fetal tissue has been removed and that there is 100 percent no chance of any remaining fetal tissue.

Q. In your opinion, Dr. Chasen, can physicians or can a physician address the risk of retained fetal tissue by checking uterine contents with ultrasound following a completion of a surgical procedure?

THE COURT: Could you keep your voice up, Mr. Hut?

MR. HUT: Sorry, your Honor. I will restate the question.

THE COURT: You allow your voice to drop and nobody can hear you.

Q. In your opinion, Dr. Chasen, can a physician address the risk of retained fetal tissue by checking the uterine contents with ultrasound at the end of a procedure?

A. The physician can address it. And the physician certainly could identify any relatively large pieces of tissue that were missing.

But even if ultrasound, the physician could not * * *.

* * * * *

[1595]

AFTERNOON SESSION
2:00 p.m.

STEPHEN T. CHASEN, resumed.

THE COURT: Good afternoon. Mr. Hut, you may inquire.

DIRECT EXAMINATION (continued)

BY MR. HUT:

Q. Dr. Chasen, before the break, you testified concerning a malpractice action filed against you with respect to a uterine rupture. From what variation of D&E did that rupture result?

A. That case was a D&E with forceps and fetal dismemberment.

Q. Have you ever perforated the uterus when using the intact variation of D&E?

A. No.

THE COURT: How about when you were a resident? You said you were sued for malpractice then, is that correct?

THE WITNESS: That's correct.

THE COURT: Did the plaintiff recover there?

THE WITNESS: I was dropped from the case. I believe the plaintiff settled with the attending physician.

THE COURT: So the case was settled?

THE WITNESS: Yes.

THE COURT: Next question.

Q. Was the claim dismissed against you before the case was settled?

A. Yes, it was.

[1596]

Q. What procedure was involved in that matter?

A. That was a hysterectomy.

Q. Dr. Chasen, do you sometimes observe the process of dismemberment D&E under ultrasound?

A. Yes, I do.

Q. When you do so and when you introduce forceps in a dismemberment D&E, does the fetus react?

A. No, not when I introduce and not when I grasp and not when I disarticulate or dismember.

Q. Dr. Chasen, in your experience, how is the fetal head extracted in a dismemberment D&E?

A. The fetal head is extracted by placing the forceps around it and crushing it.

Q. How easy is that to accomplish?

A. In some cases it is relatively easily accomplished, and in other cases it is very difficult.

THE COURT: Does it hurt the baby?

THE WITNESS: I don't know.

THE COURT: But you go ahead and do it anyway, is that right?

THE WITNESS: I am taking care of my patient, and in that process, yes, I go ahead and do it.

THE COURT: Does that mean you take care of your patient and the baby be damned; is that the approach you have?

THE WITNESS: These women who are having abortions at * * *.

* * * * *

[1600] relaxation that nitroglycerin would provide would be significant, number one. Number two, this medication can affect the cardiovascular system of the mother and make the pulse race and lower the blood pressure. And in giving a medication like this, that could relax the uterus; that relaxation could persist after the fetus is removed, and that would increase the risk of hemorrhage.

Q. Are certain of the fetal anomalies that you see, Dr. Chasen, incompatible with life?

A. Yes.

Q. Which?

A. An encephaly, some types of cardiac abnormalities, fetal cardiac abnormalities are incompatible with life. Certain syndromes, like trisomy 13 or trisomy 18, if they involve severe cardiac anomalies, are incompatible with life.

Q. What is an encephaly?

A. An encephaly is when the skull and the cerebral cortex, the front part of the brain, do not form.

Q. In your opinion, Dr. Chasen, does intact D&E offer safety advantages for women carrying fetuses with certain types of fetal anomalies?

A. Yes.

Q. Can you specify one or two such circumstances.

A. Sure. Probably the most common circumstance would be if the fetus has hydrocephalus, a condition where the head can be [1601] swollen considerably. In these cases the size of the head can make trying to apply a forcep around the head very difficult and especially risky.

In the intact variation of D&E, the head can be brought easily to the level of the cervix, where an incision can be made and the brain tissue can easily—and the fluid accumulated with hydrocephalus can easily be aspirated and the head can be brought down to a size that can easily pass through the cervix.

Q. Are there any other advantages, Doctor—

THE COURT: Excuse me. If the child has that condition, if the woman goes to term, is the child born with that condition and the head swollen like that?

THE WITNESS: Yes.

THE COURT: Does the child usually die immediately thereafter?

THE WITNESS: It depends what is causing the hydrocephalus.

THE COURT: What is the normal condition? Does the child normally die? Do they all ultimately die shortly after birth?

THE WITNESS: No. There are certain forms of hydrocephalus that are not lethal.

THE COURT: And can the condition then be treated?

THE WITNESS: If the women choose to continue the [1602] pregnancy, then for certain forms of hydrocephalus there is treatment.

THE COURT: Could the child then lead a normal life?

THE WITNESS: Again, it depends on what the underlying condition is. There is a form of isolated hydrocephalus where, with aggressive surgical treatment, there is a possibility of normal intelligence. The rates of mental retardation are much higher than in the general population.

THE COURT: Do a large number of these children, if they go to term, do they die shortly after birth?

THE WITNESS: Most cases of hydrocephalus that we diagnose in the fetus are associated with other abnormalities and not isolated. They are either lethal or a minimal chance of survival after birth.

THE COURT: So most of them would die on their own shortly after birth?

THE WITNESS: Many of them would.

THE COURT: OK. Next question.

Q. Are there any other advantages, Dr. Chasen, of intact D&E for abortions involving certain fetal anomalies?

A. Certain times, sometimes, we will diagnose a fetal abnormality and we see something abnormal but it doesn't tell us exactly what caused it or what the diagnosis is. We can tell by some of these anomalies that the prognosis may be very, very poor, and based on counseling by the appropriate [1603] specialist the patient may choose to terminate the pregnancy.

There are certain conditions that may have genetic components, and these women or these couples may be at significant risk of recurrence in a future pregnancy. In these cases it can be very important for a skilled pathologist to look at the fetus or parts of the fetus after the abortion procedure, to apply a diagnosis to the condition that we have detected in utero.

Using the intact variation of D&E, for abnormalities not involving the brain, all the tissue and the organs are preserved and they are not disrupted, and that maximizes the chance that a pathologist can identify such a syndrome, if present.

Q. Are there cases in which examination of the intact fetus offers advantage over amniocentesis for diagnosing fetal anomalies?

A. Most abnormal fetuses, if the mother has an amniocentesis, the amniocentesis will come back normal. Amniocentesis in general is used to diagnose chromosomal abnormalities, the most common of which is Down syndrome. But that is a minority of fetal

abnormalities that we can diagnose. Again, these are cases in which an amniocentesis would not provide diagnostic information.

Q. Are there any cases, Dr. Chasen, in which the examination of an intact fetus offers an advantage over ultrasound in [1604] diagnosing or assessing fetal anomalies?

THE COURT: Can I hear that question?

(Question read)

THE COURT: You mean after the abortion?

MR. HUT: Yes, your Honor.

THE COURT: Isn't that the field of a pathologist and not this doctor?

MR. HUT: I think this doctor has ample experience with patients with which he deals—

THE COURT: Is there an objection?

MS. GOWAN: No, your Honor.

THE COURT: Then go ahead and answer it.

A. Yes, there are such cases where a pathologist could examine the fetus and provide more information than we could have from ultrasound prior to abortion.

Q. Does the examination of an intact fetus offer any advantages over a fetus removed by dismemberment D&E in terms of diagnosing fetal anomalies?

A. In D&E using dismemberment, any or all parts of the fetus could be disrupted, perhaps beyond recognition. So the answer would be yes, the intact variation of D&E would offer an advantage.

THE COURT: Wouldn't it vary depending on how many parts and how much damage was done to the fetus, rather than just making an all-inclusive answer?

* * * * *

[1606] time the process of maceration, whereby the tissue in the organs can begin to decay, could have occurred, and that could interfere with pathologic evaluation.

THE COURT: What is that, Doctor, pathologic evaluation? Is that the term?

THE WITNESS: Autopsy or evaluation by a pathologist.

THE COURT: Thank you.

Q. Dr. Chasen, the way you perform intact D&E's, is there maceration involved with that procedure?

A. No, there isn't.

Q. Does intact D&E offer particular safety advantages for particular patients, Dr. Chasen?

A. Yes, it does. For women with certain medical conditions D&E would—I'm sorry. Did you ask D&E with intact extraction or D&E in general?

Q. D&E with intact extraction.

A. Intact extraction variation of D&E minimizes the risk of uterine perforation and I believe minimizes the risk of hemorrhage and can shorten the procedure time. Women who are having the procedure because of medical complications are least able to sustain the complications or to tolerate complications. So in these women, D&E with intact extraction, in my opinion, would have specific advantages.

Q. You mentioned hemorrhage. What types of patients, Dr. Chasen, are at particular risk for hemorrhage?

[1607]

A. Patients who may have decreased amount of clotting factors because of a metabolic condition or an inherited condition like hemophilia could. Patients with cancer who have undergone chemotherapy, which can prevent the body's ability to produce clotting factors, also can be prone to hemorrhage. In women that may have ruptured the membranes and may have a significant likelihood of already having an infection in the uterus, that increases the risk of hemorrhage as well.

Q. Have you performed abortions for such patients either with a shortage of clotting factors or premature rupturing of membranes?

A. Yes, I have, as well as on chemotherapy.

Q. By what procedure or variation did you perform the abortions in those cases, if you recall?

A. I don't recall.

Q. Why, in your opinion, would intact D&E offer safety advantages for women who are at particular risk for hemorrhage?

A. In that the intact variation of D&E reduces the need to insert forceps, which can be associated with uterine rupture. The insertion of forceps while removing the fetus could also disrupt the placenta prior to the fetus being removed.

And bleeding from the placental sac can be ongoing during the procedure. Using the intact variation, which doesn't involve use of forceps to remove the fetus

and which does not involve placental disruption prior to the removal of [1608] the fetus, hemorrhage would be less likely to occur.

Q. In your experience, Dr. Chasen, does intact D&E offer safety advantages over induction for women at risk for hemorrhage?

A. Yes, it does.

Q. Why is that?

A. In women at risk for hemorrhage, one common complication of medical induction is infection, and another common complication is retained placenta. Often times they coexist. Both are significant risk factors for hemorrhage.

THE COURT: Does infection ever occur in intact D&E's?

THE WITNESS: Almost never.

THE COURT: Does it ever occur?

THE WITNESS: Infection can occur in any surgical procedure, but I have never had a patient with—

THE COURT: Does hemorrhage, bleeding, occur in intact D&E?

THE WITNESS: Hemorrhage can occur in any procedure. I have never experienced it in doing a D&E with the intact extraction.

THE COURT: But it can occur?

THE WITNESS: It can occur in any surgical procedure.

THE COURT: That's all I asked, Doctor. Next question.

Q. Are there occasions, Dr. Chasen, that you have encountered [1609] where a patient needs an abortion urgently to protect her health?

A. Yes, there have been some situations.

Q. What are some of the situations that you have encountered, Doctor?

A. I have encountered women that have a dilated cervix in the second trimester or have ruptured membranes in the second trimester, and both of these conditions can be caused by an infection in the uterus or an infection can happen secondary to it. Continuing the pregnancy under these circumstances can lead to a bodywide infection called sepsis, which can be life-threatening.

I have also taken care of women that have medical conditions. One specific to pregnancy is preeclampsia, which is a complication involving hypertension and deteriorating kidney function. Although that typically happens close to term, rarely it can occur in the second trimester, and continuing the pregnancy under these circumstances could be life-threatening to the women.

THE COURT: You could be said to be doing this to save their lives?

THE WITNESS: Yes, it could be.

A. And there are also women with preexisting medical conditions, including heart disease, where, because of the physiologic condition of pregnancy, they may experience [1610] deterioration in their health, and sometimes relatively rapid deterioration of their health, and abortion is indicated as a life-saving procedure.

Q. Are these situations always life-threatening or are they sometimes health-threatening?

A. They are not always life-threatening, but they certainly could be, and they are certainly health-impairing.

THE COURT: And risk possibly to life?

THE WITNESS: Yes.

THE COURT: Next question.

Q. Would you do an intact D&E in cases where a pregnancy termination is urgently needed?

A. Yes.

Q. Are there any advantages, in your opinion, that an intact D&E would offer in such circumstances over a dismemberment D&E?

A. Again, if this woman, if my patient needs to terminate the pregnancy urgently, then she is such a patient that would be most likely to suffer from an operative complication, and these operative complications in my opinion are more common with a dismemberment form of D&E.

Q. As between induction and intact D&E, what procedure would you recommend in circumstances where a patient needed pregnancy termination on an urgent basis?

A. I would recommend D&E.

Q. Why is that, Doctor?

[1611]

A. Again, whereas normally for a D&E, especially after 20 weeks, I will do laminaria insertions for 48 hours, I can do multiple laminaria insertions in a

shorter time interval, and I can generally accomplish the procedure from first laminaria insertion to evacuation within a 24-hour window. A medical induction could take a few hours, but in many cases it could take considerably longer than 24 hours, and I don't know at the outset of the procedure what will happen.

The other safety advantages that I have cited previously favoring D&E over induction certainly apply here.

Q. Dr. Chasen, when you set out to perform an abortion, can you assure that the D&E that you perform will proceed intact?

A. No, I can't.

Q. How, then, can you say that the procedure offers advantages?

A. In some cases, in the cases in which I am able to do it based on cervical dilatation, proximity of the cervix to the vaginal opening and fetal position, it offers safety advantages. These women are typically at a more advanced gestational age.

If I could do it with intact extraction, then I could do it without introducing forceps into the uterine cavity, which increases the risk of trauma to the uterus, including rupture, and I can remove the fetus without exposing the maternal tissues to sharp edges of bony fragments and I believe [1612] I can minimize the risk of hemorrhage and shorten the procedure time.

Q. Dr. Chasen, in your opinion, is an intact D&E ever the only available procedure to terminate a second trimester pregnancy?

A. No.

Q. Does this affect your view of the safety advantages with intact D&E?

A. No, it does not.

Q. Why not?

A. In the cases in which I can do it, I have sufficient cervical dilation and the other factors I have mentioned, I'm doing it because that is the way I can remove the fetus. In my medical judgment, that is the best way I can remove the fetus and minimize the risk of complications that can harm the mother.

If I cannot use that procedure, then I will have to use forceps, multiple insertion of forceps to remove a fetus that may be relatively large. Again, all the risks of complications that I have mentioned would apply. I think I could avoid these complications by using the intact extraction variation of D&E when it is feasible.

Q. Dr. Chasen, please turn in the notebook that I have supplied to you to tab 23A. Doctor, do you recognize Plaintiffs' Trial Exhibit 23A?

A. Yes, I do.

[1613]

Q. What is it?

A. This is an article accepted for publication in the American Journal of Obstetrics and Gynecology. These are the proofs of that article, entitled "Dilation and Evacuation at Greater Than or Equal to 20 Weeks: Comparison of Operative Techniques," and I am the primary author of the study.

Q. Please put that aside for the moment. You said it has been accepted for publication. Do you know when it is scheduled for publication?

A. It is scheduled for publication in May of this year.

Q. I think you mentioned this before, but remind us again. Is the American Journal of Obstetrics and Gynecology a peer-reviewed publication?

A. It is a peer-reviewed publication.

Q. What did you and your co-author set out to do in the study that is described in Plaintiffs' Trial Exhibit 23A?

A. Our objective was to describe a large series of patients who have had a D&E at 20 weeks or beyond and to look at the characteristics of patients and compare the outcomes based on which variation of D&E was used.

Q. Did the study as you performed it make such a comparison?

A. Yes, it did.

Q. Whose idea was it, Dr. Chasen, to conduct the study reflected in Plaintiffs' Trial Exhibit 23A?

A. It was my idea.

[1614]

Q. Why did you do it?

A. I did it because any time I take a study, any time I perform a study, including everything I have published prior to this, the objective is to answer a question. There are very few resolved issues in medicine, and there are very many questions, and sometimes there is no data addressing a question and sometimes there is conflicting data. As a physician in academic medicine, if you have data that can address one of these

controversies, I think it behooves you to collect your data and publish it.

Q. Were there any preexisting published data addressing the comparisons that you and your co-authors made in the study?

A. Not that I am aware of.

Q. Dr. Chasen, what is the IRB?

A. IRB stands for institutional review board. It is a panel of both physicians and lay persons that exists at each institution that basically ensures that any research that is undertaken is ethical and protects the interests of patients.

Q. Did you need IRB approval to conduct the study?

A. I did.

Q. Did you request IRB approval?

A. I did request IRB approval.

Q. Did you obtain it?

A. Yes, I did.

Q. When did the study begin? Or when did you begin the study, * * *.

* * * * *

[1627]

A. I think a majority of the complications were genital tract lacerations, mostly cervical lacerations, superficial lacerations where the clamp was put on the cervix that required sutures. There was at least one patient that had severe nausea from presumably anesthesia that required an unplanned admission to the hospital. There were one or two patients who went

home and then had to come back to the hospital for bleeding who were found to have retained tissue and had to undergo suction curettage procedure subsequent to that.

There were three complications that we considered major, because three patients required admission to the intensive care unit. One of these patients had a uterine perforation and required hysterectomy as well as blood transfusion. Another patient had an amniotic fluid embolus, and she required admission to the intensive care unit and transfusion of blood and blood products.

The third of these patients had a bodywide infection called sepsis and a pulmonary embolus, which is when the blood clot lodges in the blood vessels in the lung, both of which are life-threatening conditions, and she was admitted to the intensive care unit as well.

Q. Just briefly, what is amniotic fluid embolus?

A. Amniotic fluid embolus is when a portion of amniotic fluid leaves the uterine cavity and enters the circulation, the blood vessels of the mother. This can induce what we think is like a [1628] severe allergic reaction throughout the body, particularly in the blood vessels in the lungs. This could cause essentially a collapse of blood pressure. The most common outcome of amniotic fluid embolus is death.

Q. Did any of what you described as these three major complications occur in the group of patients who had had intact D&E?

A. None of these complications happened in those patients.

Q. Did you find that the difference between the two groups in terms of the major complications was at a level of statistical significance?

A. It was not.

Q. Were there any differences, Dr. Chasen, in the demographics of the studies to cohorts?

A. There were differences.

Q. What were those?

A. I think the most significant difference is that the median gestational ages, the women who had D&E with intact extraction were closer to 23 and 24 weeks as a whole group, and the women that had D&E with disarticulation or dismemberment were more likely to be closer to 20 and 21 weeks. So as a whole the women with the intact extraction variation, that group were of more advanced gestation, with bigger fetuses and more placental tissue. That was one difference.

Q. Let me interrupt you. Why, in your judgment, is that [1629] difference in demographics a significant one?

A. It is significant because the rate of complications, and indeed the rate of maternal death, related to abortion in studies clearly demonstrates an increased risk with advancing gestational age. Complication rates are also higher with advancing gestational age. So the fact that women who had D&E with intact extraction were as a whole at more advanced gestation suggests that they were at higher risk for complications. They were at higher risk for complications.

Q. Dr. Chasen, were there any differences in the intraoperative variables as between the intact D&E cohort and the cohort for D&E with dismemberment?

A. We did not observe a difference in operative times or in estimated blood loss between the two groups.

Q. How about with respect to laminaria use?

A. There were more women in the D&E with intact extraction who were undergoing this procedure because they had dilated their cervix prematurely and were terminating, because they were at high risk of miscarrying prior to viability or shortly thereafter, and after counseling they chose to terminate.

These women who had advanced degrees of cervical dilation already did not require laminaria for cervical dilation before evacuation. And in that advanced degrees of dilation facilitate intact extraction, there were more of these women proportionally speaking in the intact extraction group * * *.

* * * * *

[1635] in.

(Plaintiff's Exhibit 23A received in evidence)

THE COURT: Are any of your co-authors other plaintiffs or expert witnesses in the three cases going on at the present time?

THE WITNESS: No, they are not.

Q. Dr. Chasen, before the lunch break I asked you whether you prepared patients differently depending on whether you ultimately achieved intact extraction versus D&E by dismemberment. Could you tell us whether the dilation that you apply is in all cases the same, irrespective what outcome you achieve?

A. The dilation we seek to achieve is a maximum dilation that we can. Not only will higher levels of cer-

vical dilation enable us in some cases to use the intact extraction variation of D&E, it will also make a D&E requiring dismemberment or disarticulation easier, in my view.

Q. Dr. Chasen, are you familiar with the various options for causing fetal demise before beginning the surgical evacuation of the uterus in a D&E?

A. Yes, I am.

Q. What are they?

A. There are chemicals or drugs, such as potassium chloride or something called digoxin, that can be injected directly into the fetal circulation, either directly into the fetal heart or * * *.

* * * * *

[1638]

BY MR. HUT:

Q. Based on your experience with KCL, how easy is it to accomplish a KCL injection?

A. In the easy cases it is easy and in the hard cases it can be impossible.

Q. Are there any women who you have seen for whom it, an injection cannot be done?

A. Yes, there are.

Q. Can you identify some of those, Doctor?

A. There are some women, they may be obese; they may have—the uterus may be distorted by large fibroid tumors, the benign tumors that are not uncommon, especially as women get older; where the fetal heart or the fetal umbilical cord or the amniotic cavity may be not anywhere near close proximity to the surface of the

maternal abdomen and the farther away you get the deeper the penetration that the needle is required to achieve, the more difficult these procedures can be.

There are some types of fetal abnormalities that can be associated with no production of amniotic fluid and any ultrasound guided procedure relies on fluid to surround the fetus to be able to see it. The sound waves required to see something on ultrasound need a contrast from liquid to solid and you need amniotic fluid to see what you are doing.

In cases where there is a fetal anomaly and there is no amniotic fluid it is very, very difficult to visualize [1639] either the fetal heart or the umbilical cord.

This could also be present in women who have ruptured their membranes and there is no amniotic fluid for that reason.

These are technical cases that in some cases I haven't been able to overcome.

There are also some women who are extremely afraid of needles and will not hold still for a procedure in which a needle is placed through their abdomen. They can't do it.

Q. Is it possible for a physician to cut the umbilical cord and thereby effect fetal demise prior to surgical extraction?

A. In some cases that may be possible.

Q. Do you routinely do this?

A. I do not.

Q. Why not?

A. In performing—when I perform D&E, and that's either with intact extraction or with disarticulation, my

objective is to remove the fetus, intact or not, in the shortest amount of time that it can be done.

Every time, for instance, a forcep is introduced into the uterine cavity the potential of perforating the uterus. And I would much prefer that every time I am introducing a forcep into the uterus cavity and placing this woman at risk that it should be with the objective of removing the fetus. That's why she is having the procedure.

In that trying to grasp the umbilical cord before [1640] doing this would be an extraneous step and it would expose the patient to risk, I don't do it.

Q. How long does it take, Doctor, in your experience, for the fetus to die after the umbilical cord has been cut?

A. It's not instantaneous.

Q. What effect, if any, can that delay have on the woman?

A. In waiting—if you're asking if we would wait until we could confirm a fetal demise that the heart wasn't beating in this woman who is already being subject to risks of anesthesia and in which prolonged operative times could increase the risk of bleeding and infection, then that could have an adverse effect on the patient.

THE COURT: Despite all of those reasons, Doctor, can you finally give an answer at how long does it take?

THE WITNESS: I don't know exactly how long it takes.

THE COURT: Could you give us an approximation?

THE WITNESS: During most D&Es I perform I'm not watching the fetal heartbeat while I am doing it.

THE COURT: I didn't ask you that, Doctor.

Do you know how long it would take, approximately, for the fetus to die if the umbilical cord is cut?

THE WITNESS: I would—I—I think it would take several minutes, at least.

THE COURT: Under 10?

THE WITNESS: I don't know.

[1641]

THE COURT: Under five?

THE WITNESS: I don't know.

THE COURT: Any other questions, Mr. Hut?

MR. HUT: One final question actually, your Honor. You anticipated my—almost—conclusion.

Q. Dr. Chasen, turn if you would, please, to Plaintiff's Trial Exhibit 69.

And that exhibit, your Honor will recall from earlier, is the Act.

Turn, please, Dr. Chasen, to page S-34 and to paragraph 14B of the Congressional findings. The last sentence there reads:

> "Indeed, unlike other more commonly used abortion procedures, there are currently no medical schools that provide instructions on

abortions that include the instruction of partial-birth abortions in their curriculum."

Did I read that correctly, Doctor?

A. Yes, you did.

Q. Assuming that the abortions in question referred to in this finding were the intact variation of D&E, do you believe that there is any basis for the statement by Congress in paragraph 14B?

A. There is no factual basis for this statement.

THE COURT: Well, in your school it's voluntary, right?

* * * * *

[1661]

[Dr. Stephen T. Chasen—Cross]

A. Correct.

Q. And you changed that in your next draft to, "Our data affirmed that abortion after 20 weeks' gestation with intact D & X appears to have similar complication rates as dilation and evacuation when performed by experienced physicians."

Correct?

A. Correct.

Q. And you cannot state that one technique is superior to the other, can you, Doctor?

A. Not based solely on the data in a retrospective study with certainty.

Q. Not based solely on the data in your retrospective study, correct, Doctor?

A. I cannot prove it or state it with certainty.

Q. You were also criticized for your conclusion that, "Subsequent obstetric outcomes are similar between the two groups."

Correct?

A. Correct.

Q. And that related to your finding about preterm birth, correct?

A. Spontaneous preterm birth.

Q. And because you are only able to follow up on 62 pregnancies of your group out of 363 patients, the reviewers identify a potential weakness to your conclusion on that score, [1662] correct, Doctor?

A. Correct.

Q. Now, you could have contacted the remaining 321 women to determine the absolute number of subsequent pregnancies that occurred, couldn't you?

A. We could have, but we had no guarantee of obtaining reliable data that way. That—

Q. Well, you could have asked them for permission to study the medical records to assist you in performing your study, isn't that right?

A. We could have.

But, again, I don't think that would have led to uniformly reliable data.

Q. Now, the spontaneous preterm birth occurred in your study in women who had undergone D & X at almost twice the rate of D & E by dismemberment, correct?

A. There was no statistical difference in the rate.

Q. Almost twice the rate, isn't that right, Doctor?

A. Yes. But that was not statistically different.

Q. Well, wouldn't you agree that the quality of your conclusion may be affected by the number of patients that you were able to subsequently follow who had pregnancies and delivered at Cornell?

A. No, I wouldn't agree.

Q. Directing your attention to page 39, line 20 in your * * *.

* * * * *

[1669] They're separate procedures.

Q. Directing your attention to page 95, line 2 of your deposition in this case:

> "Q Why did you use the word 'technique' in your paper?
>
> "A The title of the paper refers to dilation and evacuation at 20 or greater weeks, therefore every procedure described in here is a dilation and evacuation.
>
> "Q Doctor, why did you use both techniques on page five, first paragraph of your study?
>
> "A For the purpose of the study, to differentiate between the two techniques of dilation and evacuation.
>
> "Q And what are those two techniques?
>
> "A Dilation and evacuation with disarticulation and dilation and evacuation with intact extraction.
>
> "Q Why didn't you say that in your paper? Why didn't you describe it that way in this paragraph?

"A The first draft of the paper described it exactly that way. And then based on some feedback from reviewers it was suggested to use the term intact D&X for dilation and extraction so that the reader could create more of a contrast.

"But based on the title of the paper and based on my feeling, these are all dilation evacuation and there is the disarticulation technique and the intact dilation and extraction technique."

* * * * *

[1693] like that.

Q. Do you have any idea which of the government's discovery requests that information is responsive to, or do you have no way of telling from the billing records?

A. Again, I think the government was asking for medical record numbers, so the billing records would not respond to those in that they don't contain medical record numbers.

MS. GOWAN: Thank you.

THE COURT: Are you finished, Ms. Gowan?

MS. GOWAN: Yes, your Honor. Thank you.

THE COURT: Any redirect?

MR. HUT: Brief redirect, your Honor.

[Dr. Stephen T. Chasen—Redirect]

BY MR. HUT:

Q. Dr. Chasen, if the risk of uterine perforation is small, why do you want to minimize it?

A. It is not small to the patient in whom it occurs, I guess is the short answer. Overall, the risk is very low.

But I believe even if there is a miniscule difference in the risk based on variation of D&E, I would still want to use the one that in my best medical judgment would absolutely minimize it.

Q. How about with respect to the risk of infection; if that is small, why do you want to minimize that one?

A. For the same reason I would want to minimize the risk of perforation. Again, I would want to use my medical judgment as [1694] to which procedure would minimize that risk.

Q. Is the fetus larger on average at 23 gestational weeks than it is at 21 gestational weeks?

A. Yes, considerably larger.

Q. Approximately how much?

A. By estimated weight, probably about 50 percent larger.

Q. What does that difference mean, if anything, with respect to the safety and potential complications of a procedure at 23 weeks versus 21 weeks?

A. Again, a larger fetus through a cervix that in most cases is not dilated to a caliber that would accommodate the largest fetal part, which is the head, that would increase the challenge in removing the fetus while avoiding trauma to maternal tissue.

Q. With respect to your answer to Ms. Gowan that the gestational age variability—let me withdraw that and start again.

With respect to your answer that for each gestational week there were various spreads of procedures done intact and procedures done by dismemberment,

and your answer that those were apples and oranges, what did you mean by that?

A. In the whole cohort of 383 patients undergoing D&E at 20 weeks and beyond, the intact extraction variation of D&E was used in 120 cases, roughly about 30 percent. At 20 and 21 weeks, certainly at 20 and 21 weeks, the rate of intact [1695] extraction at those gestational ages was considerably lower than 30 percent. Starting at 22 and 23 weeks and 24 weeks, it was considerably higher than 30 percent.

To imply or to state with near statistical certainty that the gestational age distribution in the cohort that underwent intact extraction is at an increased gestational age then compared to the group that had D&E with dismemberment is not the same to say that it constituted a majority of cases at higher gestational ages. That is the apple and the orange, the majority versus the increasing proportion, the trend towards increasing proportion that we saw as gestational age advanced.

Those proportions and the statement comparing the gestational ages in the two groups were in the paper in the original version. It underwent peer review at two medical journals by six different peer reviewers and by two editorial boards, and none of them objected to that statement, because it was obvious.

Q. When you say "median," could you define that for us, please.

THE COURT: Is there an objection? All right. I don't know how he can testify as to why there was no objection.

MS. GOWAN: Thank you, your Honor. I was looking something up in the doctor's deposition tran-

script. I apologize. Could I hear the answer back, Mr. Court Reporter.

(Record read)

* * * * *

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

No. C 03-4872 PJH

PLANNED PARENTHOOD FEDERATION OF AMERICA, INC. AND PLANNED PARENTHOOD GOLDEN GATE, PLAINTIFFS

v.

JOHN ASHCROFT, ATTORNEY GENERAL OF THE UNITED STATES, IN HIS OFFICIAL CAPACITY, DEFENDANT

Monday, Apr. 5, 2004

REPORTER'S TRANSCRIPT OF PROCEEDINGS
BEFORE THE HONORABLE
PHYLLIS J. HAMILTON, JUDGE

APPEARANCES:

FOR PLAINTIFFS:

BINGHAM MCCUTCHEON LLP
THREE EMBARCADERO CENTER
SAN FRANCISCO, CALIFORNIA 94111-4003
BY: BETH H. PARKER, Attorney At Law
DEBORAH ADLER, ESQUIRE

PLANNED PARENTHOOD FEDERATION
OF AMERICA
434 W. 33rd Street
New York, New York 10001
BY: EVE C. GARTNER, ESQUIRE

PLANNED PARENTHOOD FEDERATION
OF AMERICA
1780 Massachusetts Avenue, N.W.
Washington, D.C. 20036
BY: HELENE T. KRASNOFF, ESQUIRE

FOR INTERVENOR PLAINTIFFS
CITY AND COUNTY OF SAN
FRANCISCO:

OFFICE OF THE CITY ATTORNEY
1390 Market Street, Suite 1008
San Francsico, California 94102
BY: KATHLEEN SUZANNE MORRIS,
ALEETA MARIE VAN RUNKLE,
Deputy City Attorneys

FOR DEFENDANT:

U.S. DEPARTMENT OF JUSTICE
20 Massachusetts Avenue, N.W.
Room 7128
Washington, D.C. 20530
BY: MARK THOMAS QUINLIVAN
W. SCOTT SIMPSON,
KAIJA MARIE CLARK,
Assistant U.S. Attorneys

* * * * *

[Dr. Michell Creinin—Direct]

[646]

MS. KRASNOFF: Your Honor, may I approach the witness?

THE COURT: Yes.

BY MS. KRASNOFF:

Q. Dr. Creinin, I am handing you what is exhibit 28, which is a copy of your curriculum vitae. Did you prepare this document?

A. Yes, I did.

Q. Is the information on this true and correct?

A. It is true and correct through January 15th, 2004.

Subsequently, I have been promoted to Professor of Epidemiology in the graduate school of public health at the University of Pittsburgh, coincident with my promotion to Professor in my primary department, and there is a few publications that were in press that are now published, and a few more that are in press, and a few more studies that I have funding for.

Q. And with those exceptions, is this accurate?

A. Yes, it is.

MS. KRASNOFF: We would like to move exhibit 28, Dr. Creinin's c.v. into evidence.

MS. CLARK: No objection.

THE COURT: All right.

THE CLERK: 28 into evidence.

* * * * *

[651] you perform abortions?

A. No. When looking at the upper limit, I also use

Ultrasound criteria to look at the biparietal diameter, which is the diameter of the head. And anything more than 56 millimeters in diameter is something that I don't feel I can do routinely by dilation and evacuation.

Q. Fifty-six millimeters of biparietal diameter, can you tell the court how large that is in both inches and centimeters?

A. That's 5.6 centimeters, which is about two and a half, two and a half inches. It's about like that (indicating).

Q. Where do your abortion patients come from?

A. In my private practice, the patients are referred to me by either themselves or by their health care provider, which is—and most commonly it's their obstetrician/gynecologist.

Q. And what geographic distance do you see patients from?

A. In the Pittsburgh area, there's—there are abortion providers in our city. The vast majority of which also practice at my hospital, although there's not a tremendous number.

Once you get outside of our area, there are no abortion providers. And it's—we have a catchman area of approximately three hours around the Pittsburgh area in travel time, which include women from Southern New York, Eastern Ohio, Northern Virginia and all the way into Pennsylvania to approximately the mid-portion of the State.

* * * * *

[657]

Q. Are you familiar with that act?

A. Yes.

Q. Is it your opinion that that act will ban some of the abortions that you perform?

A. Yes, it will.

Q. I want to talk to you about how you perform—those are by D&E method; is that correct?

A. Yes.

Q. And I would like to talk to you about how you perform D&E abortions and why you think it is that some of those abortions would violate the act. So I want you to walk us step by step how you perform a D&E abortion.

So, let's start with the dilation. What do you do to dilate the cervix for women with a gestational age of 14 weeks lmp or greater?

A. Most commonly between 14 and 18 weeks, I will use a type of dilator called the lamicel, l-a-m-i-c-e-l, which comes in two sizes, 3 millimeters and 5 millimeters.

And it's a firm dilator that when it—when the water is applied to it or it gets moist, actually when it gets moist after it is put in the cervix and it gets moist, it immediately softens. The primary function of the dilator is that it's impregnated with magnesium, and putting it in the cervix allows the magnesium to locally within the cervix to soften it and it activates enzymes present in the cervix to [658] soften the cervix. Normally the cervix is pretty firm like the end of your nose and the lamicel will cause a cervix over a period of as little as two hours and as much as 24 hours to soften significantly, and the length of time will vary depending upon the gestational age, the history of the patient, other factors that will come into play. Beyond 18 weeks, then most commonly I will use dilapan, d-i-l-a-p-a-n, depending on the patient's parity and other factors, for example, she's had prior cervical surgery, I may

first use lamicel for a couple of hours to soften the cervix to allow me to put an adequate number of dilapan dilators in, and then the dilators will be left in place on average about 24 hours though that may vary depending on when I saw her in the office, when she is scheduled in the operating room, if the operating is delayed a little, so there can be a little variance.

Q. We have heard testimony about osmotic dilators. That's one term people have used. Are lamicel and dilapan osmotic dilators?

A. Yes. Osmotic means absorbs or likes water. So the moment they get moist, they begin to function.

Q. And most of the other testimony has also been about laminaria. Are lamicel and dilapan the same or different from laminaria?

A. They are osmotic dilators like laminaria but they're [659] different. Laminaria is rolled seaweed and will serve the same function as dilapan, but they are just different.

Q. And why do you prefer dilapan or lamicel?

A. Especially the difference is really between the dilapan and the laminaria. I prefer dilapan because I found in my training and in my clinical experience that with dilapan I don't need to put as many dilators in to achieve the same amount of dilation than I would get with laminaria.

And it also makes it a lot easier both for me, as the clinician, and for the patient in that I can usually get in a sufficient number of dilators with one attempt as opposed to with laminaria, we may need multiple times, especially in somebody who has never been pregnant before.

Q. Do you always try to insert the same number of dilapan?

A. No.

Q. For an abortion at say 20 weeks, for example, how many dilapan would you insert?

A. Roughly five, but it, that's the—every patient is a little different. So there may be times when I only put in four and feel that in that patient's situation that four will be sufficient. And, again, there is those kinds of factors, but roughly five is what I attempt to put in.

Q. How long do you leave the dilapan in?

A. Roughly 24 hours as stated before.

Q. And what happens to the woman after the dilapan are [660] inserted?

A. She then—can go home. We give her very thorough instructions about what to expect after both dilators are placed, as well as what she can expect for after the abortion so that she has all of these instructions in writing with her.

Obviously, long before this, we went over the procedure and the options, et cetera, so these are just instructions now for once we have started the process.

So, for most women, they will experience very mild cramping. They are instructed just to use Advil or Aleve as they would for menstrual cramping. They're instructed to call us if they have severe cramps that require more attention. I would say once or twice a year I get a phone call from a patient saying that she needs something more than the Advil or the Aleve.

Whenever the patients come back at the scheduled time for their surgery, I always discuss with

them if they had any problems. And none of my patients have said, "well, I probably should have called, but I didn't." So, again, it's very rare that there's anything of any significance from the dilator placement. Usually they can go home and do normal activities.

Q. Do you ever require the woman to come back for another insertion of dilapan?

A. In individual circumstances, if I feel I didn't get enough [661] dilapan in her cervix that I would safely be able to perform a procedure, then I have to start again individualizing, and there is not a number of things I could do, the most common thing I would do is either have her come back the next morning, put in more dilapan and do the procedure much later in the day or even then delay the procedure, have her come back, put in more dilapan and do the procedure a day later.

There have been a few instances where based on circumstances related to how far she lived away, or her medical condition, I can't remember the specifics, but there have been a few circumstances where I have also given her misoprostol vaginally a few hours before the procedure to aid the dilapan, but, again, these are individual circumstances where I have to use my clinical judgment.

Q. Do you routinely use misoprostol?

A. No.

Q. You said that—you testified that you prefer dilapan because you find it is more reliable. Can you predict when you insert the dilapan exactly how much dilation you are going to be able to get?

A. No.

Q. On average, how much dilation will you try to achieve for an abortion after say 18 weeks?

A. For my patients when I do procedures, after 18 weeks, somewhere between about two to two and a half centimeters is [662] what I require. And when I remove the dilapan, during the procedure, the first thing I do is assess to see if I feel there's at least a minimum amount, enough that I am content with that I feel I can safely proceed and it's not unusual to have more than that. Again, that is going to vary by patient based on her parity and past medical history, et cetera.

Q. What is her parity?

A. Parity is how many deliveries she has had.

Q. If that happens and you remove the dilators and you find you have more than two, two and a half centimeters, is that a bad outcome?

A. No. That would make the procedure even easier. I am more interested in the minimal amount, not the maximum that I obtain.

I want—I judge the number of dilapan based on making sure I get the minimum amount without putting in so many that I make her uncomfortable or get more dilation than I absolutely need, which I have found at times can cause patients to go into labor or deliver.

And in talking with the patients ahead of time, they are choosing a D&E procedure rather than a labor induction because they don't want to go through labor. So, I am trying to balance all of those factors and deciding how many dilapan I insert for that individual patient.

[663]

Q. Now, I want you to go through what you do step by step after the cervix is adequately dilated. If it helps you at any point, we have these diagrams for you to refer to.

A. Beyond 18 weeks, I only perform those procedures in the operating room at Magee Women's Hospital. I don't do those procedures at planned parenthood.

Most commonly the patient gets a—has conscious or deep sedation by an anesthetist or anesthesiologist—I should is say anesthesiologist because it can be an anesthetist working with the anesthesiologist. In rare circumstances, the patient will receive a spinal anesthetic or even more rare general anesthetic but this is all decided ahead of time in consultation with the patient and the anesthesiologist.

Once we are in the operating room and she's placed with her legs up in stirrups in a lithotomy position and she has received her anesthetic, I will put in a speculum and remove the dilators.

I will then use a sterile cleansing solution, most commonly iodine, to clean the cervix and vagina, and the area right around the introitus. And then I will give a local anesthetic which also contains a small amount of vasopressin, which is a medicine to help constrict the blood vessels in the cervix, in the lower portion of the uterus.

I will then use a grasping instrument to hold on to the cervix, which is called a tenaculum, and then I will pull [664] on the tenaculum—actually, I will pull on the tenaculum to both stabilize the cervix, I can hold on to it, but I also want to change the position of the uterus.

Is it okay if I get up?

THE COURT: Sure.

THE WITNESS: So this diagram is kind of difficult because the vagina really isn't this long and the uterus is bigger because it has a pregnancy in it, but the uterus does sit at an angle to the vagina. And actually in an enlarged uterus at 18 weeks, the sacrum, which is here, the sacropromontory, the uterus has grown to here (indicating) where it's always going to be tipped up because it hits this bone and moved up.

So it is important with the tenaculum to pull down on the cervix to straighten that angle more so that the instruments when they pass into the uterus are going straight into the uterus as opposed to trying to maneuver this angle. That's all to try and reduce the risk of perforation.

Now, the speculum, which has blades—actually, if you imagine this straightened out, that will fit into the, what is called the fornices. And actually at times, almost prevent the uterus from coming down, so it's not infrequent that I will actually even remove the speculum and do the procedure without a speculum or use a weighted speculum, which is an instrument that just kind of hangs on the perineum.

[665]

THE COURT: Other doctors have testified as to bringing the cervix down almost to the introitus. How does that happen if there is a speculum inside?

THE WITNESS: The speculum actually almost gets pushed out. So, depending on the woman's parity, how many deliveries she has had, the more para she is, the more it comes down. That's why in those situations

you need to either sit there with the speculum halfway out or remove it and use either a weighted speculum or no speculum.

The cervix very commonly ends up very close to the opening, if not all the way down at the opening. And, again, you have to judge individually what happens. So that's what the tenaculum does.

And then—

BY MS. KRASNOFF:

Q. What do you do to evacuate the contents of the uterus?

A. The first step I take is, again, most commonly in every patient I have to sometimes do variations based on whatever is going on.

Most commonly the next step would be to rupture the amniotic sac using a cannula. Obviously if she has already had ruptured membranes, I wouldn't do that. Most commonly I would then take an 11 millimeter cannula and insert that in the cervical opening while under direct visualization with ultrasound, and use that with the suction on it to break the [666] amniotic sac to drain the amniotic fluid so all of the fluid is removed first.

In situations where I can't with the cannula break the amniotic sac, I will actually, with a small ring forceps, just grab the sac and pull on it to break the sac. So then the fluid can drain, I can then put the cannula in and drain all of the amniotic fluid. It is important to drain the fluid first to—when the uterus decompresses, in other words, remove the fluid, the uterus, the first thing it will do is to contract and that brings all of the fetal parts down into the lower part of the uterus

because my goal is just to instrument in the lower part of the uterus. I don't want to reach up high because that's how you can cause uterine injury.

So, after I drain the amniotic fluid, I'll then most commonly use bierer forceps, that's b-i-e-r-e-r, although for gestational ages that are closer to 18 weeks or at times where I may not have—where I've put in, the simplest way to say it is in gestations closer to 18 weeks sometimes the dilation is adequate enough for sopher forceps, but not bierers. They are very similar, just the size is different. Sophers are about 1.5 to 1.6 centimeters in diameter and bierer are most commonly about 1.9 centimeters. So either one can be used. Obviously, the more advanced the gestation, the more dilation there is, and the bigger forceps would be used.

Using the forceps, then I would open them, insert [667] them through the cervix opening. As I get close to the—as I begin to enter the uterus, so that I can open the instrument as widely as possible in the lower uterine segment, and it is not very wide, you are limited by the uterus itself, but just staying in the lower uterine segment, if possible, to grasp whatever is there. That's the basic concept, but then you have to use all—because all of this is done under ultrasound guidance, my goal is really to grab a lower extremity or some other portion other than the head. So what I am going to do is vary by the fetal position.

If it is head first, it's very, very, very difficult to try and grasp the head as the very first thing. So, with every D&E, the way I have been taught, the way I have always done it, the way I have always taught it is to try and grab a lower limb to convert the position to breech and then proceed with the evacuation. If it's already

breech, or if it's transverse, that's easier to grab a lower extremity.

After grabbing the lower extremity, I am going to pull the pregnancy or pull whatever part I have grasped through the open cervix until there is resistance from the lower uterine segment and the internal os. My goal is to try and remove the fetus as intact as possible. The fewer passes, the safer it is for the woman.

So, as I pull down, the uterus is going to tell me how far I can go just by the resistance I get. So when I meet [668] resistance, I will continue to pull, and it's the pressure of the fetus against the lower uterine segment that actually results in dismemberment of the fetus. And where that is going to happen on the fetus will vary from patient to patient.

As the fetus—tissue that I am holding on to gets —is in—

Q. I want to break it down. You just told us a lot of things you do.

A. I am just proceeding through.

Q. That's okay. I am going to stop you and ask you some questions about how much—what you've told us so far.

A. Okay.

Q. I just want to make it clear, you are always doing post-18 week procedures under ultrasound guidance; is that correct?

A. Correct. I use ultrasound guidance for all of my procedures where any instruments are placed in the uterus other than a suction cannula.

Q. Can you explain why it is that you think it is beneficial to grasp a lower extremity regardless of the presentation of the fetus?

A. As I said earlier, it's incredibly difficult to grasp the head first. The head, until about 34 weeks of pregnancy, is much larger than any other part of the fetus.

So, if I am trying to grasp the head and there's other small parts behind it, it just becomes a [669] difficulty in grasping the head.

So, again, from the way I was taught from the very beginning, and it is almost common sense if you think about it, you convert the fetus to breech so that's where especially using ultrasound guidance, the safety comes in because I am going to watch my instrument, guide it to an extremity, so that when I teach the procedure or i ever talk about it, this is a standard way of doing dilation and evacuation.

Q. So is it sometimes the case that the fetus is presenting in a head first or vertex presentation and you would grasp a lower extremity and rotate the fetus so that it is feet first?

A. Virtually all the time. It is on rare circumstances that I get the head first and it's usually only because the head is so applied to the cervix I can't really get passed it to try and get a lower extremity. And I can think of once or twice in my entire career that I can think that I have done that.

Q. This is because you think it is safer for the woman to grasp the lower extremities first; is that correct?

A. Yes, that's the way the procedure is done.

Q. Are you aware, Dr. Creinin, that one of the Congressional findings of the act that's at issue in this case States that converting the fetus to a breech presentation increases certain risks and some of the risks they name are uterine rupture, abruption and amniotic fluid embolus.

Do you agree with that finding?

[670]

A. Not at all.

Q. I want to go through each of those risks and have you explain what they are and why you think it is that that finding is incorrect.

A. Okay.

Q. What is abruption?

A. Abruption is premature separation of the placenta from the uterus. And that wouldn't apply in the situation because my goal is to remove the placenta as part of the procedure. And sometimes it comes out as one of the first things I remove, sometimes it comes out in the middle of the procedure, I am going to grasp whatever I am grasping, and when I get a hold of it, I am going to remove it. So those findings apply to cases where a delivery is being done with the intent of a live fetus being born, but separating the placenta from the uterus is an innate part of the D&E and has no implication here at all.

THE COURT: Excuse me. In a live birth situation, you don't want the placenta to come out even in part before the baby comes out.

THE WITNESS: Exactly because the fetus is getting its oxygen and nutrients through the placenta.

And an example would be a woman at 30 weeks of pregnancy starts to have bleeding because the placenta separates prematurely. She can not only lose a lot of blood, but the baby could die. So that [671] that would be a potentially catastrophic situation. Or there are maneuvers done at term, for instance, internal podalic version, which you have heard about, at term and the placenta separated and the fetus was unable to be removed right away, but the fetus would be stuck in the uterus with the placenta separated and no way to get oxygen. So at term, that would be important, but as part of an abortion procedure, it's completely irrelevant.

MS. CLARK: Your Honor, I am going to object on the basis that the risks, so-called risks associated with or lack or not—risks or no risks of converting the fetus, that wasn't set forth in the expert's report, we didn't talk about it at the deposition. I think this is outside the scope of his expert report.

MS. KRASNOFF: His main opinion is that the banned procedures are the safest way for him to dispute the act which is that it's unsafe for the woman to have the procedure performed in the manner set forth in the act.

THE COURT: Well, is this one of the things that was discussed? I mean, I don't have all of the materials in front of me. I will have to depend upon you all to let me know.

Her objection is one of lack of notice, I assume?

MS. CLARK: Yes.

THE COURT: This is one of the areas that you were going to bring out through this doctor?

* * * * *

[673]

THE COURT: You withdraw your objection?

MS. CLARK: I withdraw it.

THE COURT: All right.

BY MS. KRASNOFF:

Q. Move on to amniotic fluid embolus. Dr. Creinin, what is amniotic fluid embolus?

A. That's when the amniotic fluid enters the woman's circulation usually through a sinus, which is a large opening, in the lining of the uterus that would be part of the way the blood was getting to the placenta from the woman.

So, again, at a D&E procedure, since the first part is to remove the amniotic fluid, that's a moot point since it's already been removed as part of the procedure.

Q. So, just to be clear, it's your opinion that turning the fetus in utero would breech the presentation in a D&E doesn't cause any greater risk of amniotic fluid embolus than if you do not do that conversion?

A. First of all, amniotic fluid embolus is so incredibly rare, it would be hard to show any increase risk at this gestational age.

THE COURT: Can you describe what it is again?

THE WITNESS: I am sorry. The amniotic fluid, when it gets into the woman's bloodstream, so it gets in through some openings in the uterus. So if it gets into her bloodstream, it will first go up to the heart and then into the [674] lungs. And in the lungs, I apologize, I

didn't say this earlier, in the lungs it causes an incredibly fast tissue reaction that will cause her to quickly not be able to exchange air across her lungs. She will become hypoxic, which means has low oxygen, go into a respiratory arrest and then cardiac arrest. It can lead to—the heart has its own little brain that makes it pump or it makes it beat at certain rates so the electrical system of the heart can still be working, but the heart muscle itself doesn't respond to it at all. So if an EKG Monitor was on the woman, it would look like everything is normal, but her heart isn't pumping. These are things that can occur with amniotic fluid embolus.

THE COURT: Is it fair to assume then, if there was such an occurrence, that that would necessarily follow from a perforation of the wall of the uterus? Is there any other way for it to get—

THE WITNESS: Not really. It's just from the openings that are there, where most commonly where the placenta is attached. So, it's not from a hole in the uterus, it could just be that when the placenta detaches and some of those openings are exposed that amniotic fluid could get in.

Again, with D&E procedures, the amniotic fluid is primarily removed first before any of those things occur.

THE COURT: Okay.

THE WITNESS: It's an incredibly rare occurrence at [675] term let alone even at this gestational age.

THE COURT: Thank you.

BY MS. KRASNOFF:

Q. What would be the difference of why that would occur at term versus in a D&E? You've testified to this, but just to make it clear.

A. At term, the amniotic fluid is, number one, still there, and then even in a woman with ruptured membranes, the amniotic fluid primarily comes from the fetal urine, so the fetus is still peeing inside. And also as a woman going through delivery, if you can imagine the head going through the cervix at term, it wedges in, so as it pees inside, the fluid is going to rebuild up inside the uterus. So that if abruption was to occur during delivering, there still would be fluid there. Whereas, again, during an abortion at this point in pregnancy, it is relatively a moot point. It is an incredibly rare occurrence to start with.

MS. CLARK: Your Honor, I just want to make my objection. I agree with counsel that on page 163 the question was: in doing that, was there any concern by reaching around the part with forceps—

THE COURT: Slow down.

MS. CLARK: I'm sorry.

I am rereading from the deposition page 163, lines 9 through 14. And I think the testimony of converting the breech [676] at term versus converting to a breech position during an abortion, I think that goes beyond the scope of his deposition testimony.

THE COURT: Well, counsel, I will allow it at this time. You withdrew your objection previously. It seemed the appropriate thing to do is given the excerpt, perhaps we will move on to some another subject, I am not going to strike his testimony.

MS. KRASNOFF: A few more questions about turning the fetus, then I will be moving right along.

BY MS. KRASNOFF:

Q. Does turning the fetus increase the risk of rupture or trauma to the uterus?

A. Not at all. That's a part of D&E procedures. So all of the data that has ever been published includes that information.

And the act itself potentially could cause uterine rupture, but any procedure, any part of the procedure, just like labor induction, just like anything else, so it's more of a relative term. Could it increase at more than something else? No. It's just that the act itself can cause rupture of the uterus just like any other part of the D&E could.

Q. Just to be clear, by "act" you mean little "a" act of turning the fetus, you're not talking about the act as we've talked about in this case?

[677]

A. I'm sorry, the action.

Q. I just wanted to be clear.

My final question on this topic, is that the Congressional findings state that a leading obstetrics textbook says there are few, if any, indications for turning the fetus in utero other than for delivering of the second twin.

Are you familiar with that?

A. Yes, I am.

Q. Is that relevant here?

A. No. Again, that—

MS. CLARK: Objection on the basis of who's to say what is relevant or not relevant. I think that calls for a legal conclusion.

THE COURT: Sustained. Rephrase.

BY MS. KRASNOFF:

Q. Do you think that there—that that statement that there are indications in a D&E for turning the fetus in utero?

A. I don't agree with what was stated in the congressional findings that—I am confused. I don't agree with the congressional findings. Is that sufficient?

Q. The congressional findings say there are few, if any, indications. But you've testified that you do turn it. So, I am asking if you believe there are indications—

A. Doing a D&E is a indication for turning it.

[678]

Q. And is that—are you familiar with that textbook?

A. Yes, I am.

Q. Is that speaking about delivery at term?

A. Yes, it is.

Q. So, moving along, once you've located and grasped the lower extremities and turn the fetus if you need to, what do you do next?

A. Pull with the instrument that I am using to remove the fetus with the attempt to remove the fetus in as few passes as possible. So until I meet resistance from the lower uterine segment, I will continue to pull.

Q. Why—

A. And once I meet resistance, I will then, while holding on to the fetus—minimal rotation, but just kind of try and ease those parts through the cervix to allow whatever's meeting resistance to try and slowly get through the cervix.

The fetus will either continue to come or will begin to break apart. It will break apart wherever or whatever it is. It may be in the middle of the leg, it may be at the abdomen, it may be at the chest, just depending on the dilation and the size of the fetus, et cetera, just on that individual case.

Q. Does it ever happen that you are able to extract the fetus intact or relatively intact up beyond the navel?

A. Yes. The level of the umbilicus, yes.

[679]

Q. Can you explain what that is?

A. There actually is no navel in a fetus. You and I have a navel because our umbilical cord was gone. The fetus has an umbilicus, but no navel because it still has the umbilical cord attached.

Q. At that point when the fetus has been removed, we are going to use "past the navel" because the act uses that.

A. Correct.

Q. You understand—

A. I understand the intent, correct.

Q. You understand it to be the umbilicus?

A. Yes.

Q. Would the fetus still have a heart beat?

A. Yes.

Q. Then what would you do next?

A. I would reach into the lower uterine segment and grasp whatever part is there and then continue to remove the fetus.

If, once—usually, if the fetus has been dismembered, the last part is the calvarium, the head. At that point, I will grasp the head and crush it like other parts of the fetus and remove that.

I will then, if the placenta hasn't been removed, reach up and remove the placenta. I'll then, using the suction cannula, suction the lining of the uterus to ensure that the lining that was there as part of the pregnancy has been removed [680] and any parts of the placenta that still may be present are removed. I will then take a really a blunt curette, dull curette to feel the lining of the uterus, again, still under ultrasound guidance to ensure that it feels like everything has been removed to me, and then look and make sure that the bleeding is at a level that I would expect it to be, remove the tenaculum from the cervix, make sure there's no cervical tears or lacerations. If there is a speculum, I would remove it at that point and then the procedure is completed.

Q. Does it ever happen that in grasping the fetus you're able to remove the fetus intact or relatively intact all the way up to the calvarium?

A. Yes, on occasion.

Q. If that happens, would you do anything differently to complete the procedure?

A. If the fetus is intact up to the calvarium, there's two things I could do.

One would be to continue to pull, and usually it comes apart at the level of the neck, or I can insert, what I would I have done is insert scissors through that part of the head under direct visualization, inserted the 11-millimeter cannula that I used before and drain the brain tissue and then the head comes through the opening.

I have done that on a few occasions. Most commonly [681] it's the first.

Q. The first meaning?

A. Just that it separates, the body separates from the head.

Q. And back to the example where it is removed intact or relatively intact up to the navel, how frequently, in your practice, does that happen?

A. At least once a month.

Q. Does it ever happen that you've disarticulated some part of the fetus, but then on another pass with the instruments you are able to remove the fetus passed the umbilicus?

A. Yes. Sometimes I've made an initial grasping, have a foot or portion of the lower extremity come off, and then with the second grasp, it would still come out past the level of the umbilicus. So it still would be mostly intact.

Q. Could it still have a heartbeat at that time?

A. Yes.

Q. And what would you do next if that had happened?

A. I'd still continue in the same methodology because my objective is to remove the pregnancy from the uterus.

Q. And when you begin the procedure, can you anticipate how much of the fetus you are going to be able to extract without disarticulation?

A. Not at all. It is going to vary from woman to woman based on her parity and how the cervix responded to the dilators. My main objective is the minimal amount.

[682]

Q. Would you ever take any steps to make sure that it's not removed intact?

A. Can you—intact up to the level of the umbilicus you mean?

Q. Yes.

A. No.

Q. Do you think there is anything safe about removing the fetus intact up to the umbilicus or to the calvarium?

A. The fewer passes, i feel the safer it is. Yes, I feel it's safe.

Q. I actually asked if it was unsafe.

A. I am sorry, I thought you said safe.

Do I think it is unsafe? No.

Q. You mentioned that sometimes you use scissors to instrument in the base of the skull. Is there anything that is unsafe about the insertion of scissors into the base of the calvarium?

A. When I do it for my patients, no, it is under direct have you ever had an injury or a complication from an abortion where the fetus was removed intact up to the calvarium?

A. No.

Q. And you said—we talked about the procedure is complete. How long after you completed the procedure before the woman can [683] go home?

A. On average it's about two hours.

Q. I want to put up on the easel—

MS. KRASNOFF: if I may I approach, your honor?

THE COURT: Yes.

BY MS. KRASNOFF:

Q. —copy of the operative portion of the act.

If you would read that, Dr. Creinin, not out loud, to yourself is fine. We talked at some length about the D&E abortions that you performed. I would like you to explain to the court why it is that you think some of the D&E's that you performed would violate this definition of partial-birth abortion?

A. Well, primarily it's in the case of a breech presentation, that any part of the fetal trunk past the navel is outside of the body of the mother. As I was alluding to earlier with the other diagram, it is very common for the cervix to be down far in the vagina so that as the fetus is being removed through the cervix, the fetus would be, have the fetal trunk past the navel outside of the body of the mother relatively commonly.

So that right there would violate the act because the purpose of my act is to kill the partially-delivered

living fetus because that's the objective of the abortion. And anything I would do once it's past the level of the navel, would be an overt act because I would be doing something * * *.

* * * * *

[689]

BY MS. KRASNOFF:

Q. Actually, based on your experience, you mentioned the liver transplant as well. Is there another case, an actual patient that comes to mind there?

A. There was—I have had a patient who had fetal demise where the situation arose, and in that situation, I would have chosen to do an intact removal if we got to that point, but she passed away.

Q. And can you explain why in that case intact removal would have been preferable?

A. Because her liver had completely failed, and she had no way of clotting.

Q. Would it have been safe to do an induction in that case?

A. No, that would have killed her without a doubt in trying to get her through the induction.

You have—inductions is a very prolonged process, and there is going to be bleeding throughout the induction. So as the fetus begins to pass through the birth canal or the placenta begins to separate, here is a woman who can't clot at all. I would want to do a procedure on her under very controlled circumstance than to make the procedure go quickly. You have a period of bleeding, be a short time, to have support people around. There is a benefit of being in an

operating room where it's like an intensive care unit, in a sense. You have the ability to handle things acutely. [690] so a procedure in that situation would be preferable. And these are situations also where the maternal fetal medicine specialists in our department are part of the consulting team, and the majority of the patients like this that have severe, actually almost all of the patients with severe medical conditions are referred to me by the maternal fetal medicine specialists in our department.

Q. We are going to switch topics a little bit. I know you were looking at the clock, your honor. Do you want to go to Four?

THE COURT: I am assuming you will be finished by Four with the direct?

MS. KRASNOFF: With the direct? Yes, you're incorrect.

THE COURT: We will go to Four.

MS. KRASNOFF: Close though.

BY MS. KRASNOFF:

Q. We are going to switch and talk about cervical incompetence.

What is cervical incompetence?

A. Cervical incompetence is a weakening of the structure of the cervix that would not allow it to stay closed with pressure from a growing pregnancy.

So, the cervix is actually about 80 percent connective tissue and 20 percent muscle, whereas the uterus is [691] all muscle, or virtually all muscle. So that connective tissue, also called ground substance, and it's very strong tissue. So, the inability of that strong

tissue to just maintain its structure when there is a lot of pressure from a growing pregnancy, cervical incompetence, and it results in painless dilation of the cervix.

Q. Are you aware, Dr. Creinin, that the findings of the partial-birth abortion ban act state that the amount of dilation needed in order to be able to remove a fetus intact up to the calvarium increases the risk of cervical incompetence?

A. Yes, I am.

Q. Do you agree with that finding?

A. No, I don't.

Q. Can you explain why not?

A. Well, first, there is a physiologic basis. Labor is a process where the cervix dilates to 10 centimeters, if you take a woman at term. It's usually 10 centimeters over a relatively short period of time.

Most women go through labor would hope it would be a very short period of time, but in a D&E procedure, we are talking about slow dilation to two to two and a half centimeters over a period of 24 hours. So, it doesn't even make physiologic sense that it would cause more damage to a cervix to have a slower dilation in a longer period of time or slow dilation to a lesser amount compared to a greater dilation [692] in a shorter period of time. So, there is no physiologic basis for it. Then the literature that is available, when you look at the literature, there are a couple of studies that are—that report on a few pregnancies, relatively few, 60 to a hundred or so, of women who had procedures and then had subsequent pregnancies. And the rates, there was no increased rate of pre-term birth or pre-term delivery or cervical incompetence in those women.

Now, those studies aren't large enough to make conclusions, but if you take those studies that are available along with the common sense physiology of what's going on, I think there is no way you could determine that there would be cervical incompetence. There is definitely no studies to say it does, and it doesn't make any sense to say that it would happen. And you would—because the common sense part of it is that it wouldn't happen, you would need really large studies to prove that it does.

MS. KRASNOFF: May I approach, your honor?

THE COURT: Yes.

BY MS. KRASNOFF:

Q. Exhibit 17, the Kalish Article.

Dr. Creinin, I handed you what has been marked as Exhibit 17, which is an article by doctors Kalish, Chasen and several others, which is entitled "impact of mid-trimester [693] dilation and evacuation on subsequent pregnancy outcome." This article was published in the American Journal of Obstetrics and Gynecology, Volume 187 in October of 2002. Are you familiar with that article, Dr. Creinin?

A. Yes, I am.

Q. Is that one of the studies you talked about that use relatively small numbers of women?

A. Yes, it is.

Q. Can you tell the court, please, about that study?

A. In this study it was a retrospective review, which means they looked back on charts of 600 women who had D&E procedures, and 96 of these women had subsequent pregnancies. So they looked at those 96

pregnancies, and—to see what the outcomes were, and specifically related as cervical incompetence.

There were five women—I am sorry, there were 10 deliveries that were before 37 weeks, five of which were obstetric or maternal indications for them. There were five women who had prophylactic cercloges, which are stitches in the cervix to keep them closed. Those five—four of those women had a history of cervical incompetence that preceded the D&E that they had previously, and one other person had des exposure, and that's why her doctors chose to put in the cerclage. That's also an increase risk factor for cervical incompetence.

So none of those patients had evidence of cervical [694] incompetence. And there were no patients who received any emergency cerclages meaning that experienced cervical incompetence, so what they found in these 96 women is that there was no evidence of cervical incompetence.

As I said, that is a small study, but at least it gives you some idea that it fits in the theoretical understanding of what you would expect physiologically.

Q. Just to be fair, what were the gestational ages of the women involved in this study?

A. Fourteen to 24 weeks.

Q. What kind of abortion procedures had they had?

A. Dilation and evacuation.

Q. Is it your understanding that they received osmotic dilation prior to the procedure?

A. For the dilation and evacuation?

Q. Yes.

A. Yes, it is.

THE COURT: All right. I think this is an appropriate time to stop.

MS. KRASNOFF: Okay.

THE COURT: It's 4:00 o'clock. All right.

Doctor, you are excused. You may step down.

We will adjourn until tomorrow morning at 8:30, and we will have a regular day time-wise tomorrow.

MS. KRASNOFF: That won't be a problem.

* * * * *

[Tuesday, Apr. 6, 2004]

[700]

THE COURT: All right.

All right, Ms. Krasnoff.

MS. KRASNOFF: Yes.

(thereupon, Dr. Creinin resumed the stand.)

[Dr. Mitchell Creinin—Resume Direct]

BY MS. KRASNOFF:

Q. Good morning, Dr. Creinin.

A. Good morning.

Q. Yesterday you gave some testimony. I just wanted to clarify one thing about that. You stated that you believe there may be liver patients for whom an intact removal or an attempt to remove the fetus intact may be preferable. Is there a reason why you believe in your practice you would see those sort of patients?

A. Well, patients with liver transplants or liver problems. At the University of Pittsburgh where I practice is pretty much the liver transplant capital of the world.

It is where things pretty much were developed and started, and so they get patients who come from all over the world to get their liver transplants and other transplants.

Q. And when we broke yesterday we were talking about cervical incompetence and about—we had just finished discussing the study by Drs. Kalish and Chasen and others about D&E abortions and whether they lead to cervical incompetence.

Are you familiar with other studies that relate [701] specifically to D&E abortions and that issue?

A. There is one other study by Schneider, which is a series similar to the Kalish study, which just comments on follow-up with patients after D&E, showing that—I believe it was around 60 odd patients.

MS. KRASNOFF: If I may, approach your honor.

THE COURT: Yes.

MS. KRASNOFF: This is learned treatise four.

BY MS. KRASNOFF:

Q. Dr. Creinin, this is an article by Dr. Schneider and several others, entitled:

> "Abortion at 18 to 22 weeks by laminaria dilation and evacuation," published in Volume 88 of Obstetrics and Gynecology in September, 1996.

Is this the study you were referring to?

A. Yes.

Q. Can you explain that study briefly and its conclusions?

A. This was a case series of 171 dilation and evacuation abortions. And in the findings, in the results at the time of the report there were 61 women who were pregnant following the D&E procedure, and none of those women had cervical incompetence. And the authors specifically comment on it on the last page of the article.

Q. And those women had abortions by the D&E method; is that correct?

[702]

A. Yes, it is.

Q. And what were the gestational ages of the women when they had the abortion?

A. Eighteen to 22 weeks.

Q. Now, we have talked about these two case series which demonstrate or conclude that there's no increase incidences of cervical incompetence or at least suggest that; is that correct?

A. Yes.

Q. Do you know of any date that suggests that osmotic dilation prior to a D&E does lead to cervical incompetence?

A. No.

Q. At the beginning of your testimony yesterday, you testified that you have conducted gynecologic research yourself; is that correct?

A. Yes.

Q. What is a prospective randomized trial?

A. That's a study where there are two or more groups assigned to a specific treatment or intervention, and that assignment is random, either by like similar to flipping a coin, and most commonly today we use computer-generated tables to provide the randomization.

And the treatment or the intervention is one in which the study participant and the people performing the study have no choice or say on what treatment or intervention they [703] get.

And then, the participants are followed prospectively, meaning from the time of the intervention forward, to see what happens from the intervention or treatment.

Q. And have you yourself ever designed and conducted prospective randomized trials?

A. Yes.

Q. How many have you been the principal investigator for?

A. Eight for which I have been the person who designed, carried out, not just being a principal investigator at my center for a study that is going on in a lot of other centers, but actually eight that I have been in charge of completely.

Q. In addition to the eight that you have been in charge of, have you been involved in others?

A. Yes.

Q. Do you know approximately how many?

A. More than 20.

Q. And have you ever designed and conducted, where you were the principal investigator, a prospective randomized trial specifically related to abortion methods?

A. Yes.

Q. And can you describe that study, please?

A. That was a study looking at early abortion methods, medical abortion versus surgical abortion. And this was a study in [704] women up to seven weeks of pregnancy, so it was very early. But the study was looking at randomizing women to one of the two treatments. And the criteria for enrollment in the study was that women had to have no preference for which method they wanted.

They, the women, went through counseling first about the different options. And then, if they truly felt they had no preference, and they met the other entry criteria they could be enrolled in the study.

Q. And how many women were you trying to enroll in the study?

A. The sample size estimates—sample size estimates for the outcomes I was looking at were about a hundred women total.

Q. What was your experience in trying to do that?

A. After two years we stopped the study early because we could only enroll 50 women after two years. We interviewed or had not interviewed, but had approximately a thousand women contact us about the study. And after reviewing the options with them and the different options for abortion, only 50 after two years felt that they truly had no preference.

Q. And you spoke to all or someone spoke with all thousand of those women?

A. Correct.

Q. Based on your experience with this study, do you have an opinion about whether it would be feasible to conduct a prospective randomized trial about abortion methods after 16 [705] weeks of gestation?

A. Yes, I do.

Q. And what is that opinion?

A. If I go back to the study a little bit, even for those 50 women, once they enrolled in the study, I then did further very sophisticated testing to see if they truly had a preference. And actually 35 of the 50 really did have a preference once you could figure it out.

So there were truly only 15 women who had no real preference as to which method they preferred out of a thousand over two years. And this is in women up to seven weeks. And there is a much larger pool of women available in the U.S. when you look at the number of abortions done in the U.S. and at what gestational ages.

So when you start to look, then, at later gestational ages, the ones we are talking about after 16 weeks, there is relatively significantly fewer women who are having abortions at that time.

So to have a prospective randomized trial would be unfeasible, unreasonable and impossible to do.

Q. And if you were trying to prove safety, specifically, of various methods of abortion after 16 weeks, is there a reason that that would be difficult, as well?

A. All the labor induction, D&E, they are all very safe methods. And we have heard there is a lot that goes into a [706] women's decision as to which method she prefers. And in an individual circumstance, both personally for her, as well as medically. And when you start to look at outcomes, when the outcomes you are looking at are very rare or they don't occur very frequently, if you are looking at serious morbidities—with any of these methods you are looking at things that are 1 to 2 percent at the greatest.

So for methods that are very safe, very effective, in general to try and prove a difference or prove that one is better than another for all comers, for all people would be impossible. The sample sizes would be huge.

I have done some calculations, can I—

Q. Sure.

A. I am happy to share this.

THE COURT: Has this been made—

MR. SIMPSON: This has not.

THE WITNESS: I did this on my computer a couple days ago, and I am happy to share it. But it's just that if you had an outcome that was 1 percent for one group and one-half of one percent for another group that you were trying to say there is a difference those outcomes, you would need over 5,000 women per group to prove that was statistically significantly different. So, if you were at 2 percent versus 1 percent, you are still over 2500 women per group. And then, to get people [707] who could do research and to get women who then were interested and willing to be randomized, it is just a completely unfeasible study.

There is another study we just finished that was funded by the NIH, where it was looking at miscarriage and the treatment of early miscarriage. And women were randomized to medical or surgical treatment. And there were four very large, well-respected centers that were awarded the contract by the NIH to do the study with the goal that we would enroll 800 women over about a year-and-a-half between the four centers.

And in over two years the four centers could only get a little over 600 women. And we recalculated our sample size needs and felt that was enough. But that was in early miscarriage.

So to get women to say they are willing to be randomized between surgical and medical method because they have preferences and there are differences for them as individuals, is, again, unfeasible at the gestational ages we are talking about for D&E versus labor induction.

BY MS. KRASNOFF:

Q. And other than your own experiences, do you rely on any other studies in reaching the conclusion that a study of procedures after 16 weeks would be extremely difficult?

A. There was a study just published by David Grimes from North Carolina that looked at the feasibility of this issue and—

[708]

Q. Would it help if I showed it to you?

A. Yes.

MS. KRASNOFF: If I may approach, I would also like to share his notes with counsel.

THE COURT: If you would. And what is it you are referring to?

MS. KRASNOFF: This is learned treatise 11.

BY MS. KRASNOFF:

Q. Dr. Creinin, that is a study by Dr. Grimes at the University of North Carolina and others entitled:

> "Mifepristone and misoprostol versus Dilation and evacuation for midtrimester Abortion: a pilot randomised, controlled trial."

This was published in the British Journal of Obstetrics and Gynecology just this February, 2004, in Volume 111.

Is this the article you are referring to?

A. Yes.

Q. What was Dr. Grimes comparing?

A. The primary objective of the study was to assess the feasibility of randomizing U.S. women to these two methods of abortion. So labor induction process versus dilation and evacuation.

Q. Okay.

A. And the goal was in assessing the feasibility to —they [709] calculated the sample size of 60 women that they would need to compare the two from a feasibility standpoint, and they also established that if they could not enroll at least 20 women in twelve months, or 40 women in 24 months, they would consider it unfeasible and stop the study.

Q. What was their experience?

A. In twelve months, they could only enroll 18 women, because the majority had a preference for what they wanted to have as far as their method of abortion.

Q. What was the gestational age range that Dr. Grimes was looking at?

A. These were women, I believe, up to 20 weeks, but I need to—14 to 19 weeks. So between 14 and 20 weeks.

Q. And why does Dr. Grimes' experience support your view about the feasibility of randomized trials after 16 weeks?

A. If you were going to do studies of this nature you would need well-respected researchers and well-respected institutions that know how to perform research appropriately. And the Institution where Dr. Grimes is and Dr. Grimes himself is an incredibly well-respected mentor, researcher, teacher. And I can think of nobody who would be a greater example of how to construct such a study. And if they couldn't find it feasible there, I wouldn't—and "feasible" meaning 20 people in a year. And they couldn't even get that. So I can't see this as being feasible anywhere.

[710]

Q. I want to switch gears a little bit now and talk to you about induction abortions.

You testified you no longer do inductions; is that correct?

A. Yes.

Q. But you did testify you are also the co-author of a chapter in a textbook about inductions; is that correct?

A. I am an author, and the update is as a co-author.

Q. Why do you not do inductions as a part of your current practice?

A. Because in my current practice I believe in my hands that a D&E is safer for a woman than a labor induction. And when we look at the practice at my institution, because in our department we also, in general, feel that same way.

The majority, vast majority of women at our institution, whether it be for elective or maternal or fetal indications that have a termination at this point in pregnancy have a D&E procedure, or are counseled about the options and choose a D&E.

Relatively few inductions are performed. Because there are so few, it's my feeling, that it's best left at that point to the people who are doing them more than me.

There's also an issue of obstetrics malpractice coverage. But that became secondary because that only became an issue about two years ago. But I haven't done inductions [711] for nearly 10 years just because there are so few. I would much rather have the maternal fetal medicine specialist do those procedures, whereas my partners and I would do the—provide the dilation and evacuation services are the people who provide those services.

And the vast majority of people are referred to us for D&E after counseling, and primarily by the maternal fetal medicine specialists and genetic specialists.

Q. Do you ever refer any of your patients for inductions?

A. Yes.

Q. And in what circumstances?

A. It's not unusual for patients to be referred to me by their obstetrician/gynecologist, and they haven't had full consultation with genetics or maternal fetal medicine or both.

So an important part of my counseling with them is to go over their options, as I do with every woman. And there are people who feel, whether it be for their individual, personal reasons or whatever the circumstances may be, that they prefer a labor induction abortion. And by all means I would not deny that to them. So then the maternal fetal medicine specialist perform the labor induction.

Q. If you can approximate how frequently after counseling do women choose induction?

MS. CLARK: Objection, lack of foundation, unless he [712] is talking about his own practice.

THE WITNESS: In my own practice?

BY MS. KRASNOFF:

Q. Yes.

A. About a year, one patient a year. Again, most of these patients already—a lot of these patients already had been counseled, but I can speak in general for our institution. It is very rare that we perform labor induction abortions.

Q. Are there medical situations where you think a surgical abortion would be preferable for a patient to an induction?

A. Yes.

Q. Can you give some examples of those?

A. If a woman has had prior surgery on her uterus, then depending on what kind of surgery and where the surgery was, it would be definitely preferable not to have her labor, if at all possible.

Can I go up to the diagram?

THE COURT: Yes.

THE WITNESS: In the—when the uterus is contracting, whether it be at term or if we give medicines to make the uterus contract to cause labor, the strongest part of the uterus is the part up at the top. And the part that is lower doesn't contract as strongly. And it makes sense. The uterus wants to contract from the top down to expel the fetus, as part of going through labor or induction abortion.

[713]

And so this muscle up here (indicating) contracts much more strongly. If an incision has been made in the upper part of the uterus, like with a myomectomy with fibroids have been removed in the past, or if a woman had a cesarean section with a scar included the upper part of the uterus, we recommend—in fact, we almost insist with women that if they are looking at having a delivery that they cannot have a vaginal delivery.

And we will go to large extents in general obstetrics practice to prevent them from going into labor by checking fetal lung maturity early, beginning around 36 weeks so that they don't ever go into labor. If the fetus lungs are mature, then we do their C-section so they never have to have labor if they have had an incision up here (indicating). And the same

thing applies for labor induction abortion. Where a woman has had surgery in this part of the uterus, I would not want to give her medicines that would make her contract so strongly that it puts her at those same risks. If a woman insists that she is willing to take that risk, then we would still discuss it further. I have never met a patient who has said:

> "I insist on taking that risk as opposed to having a D&E."

But those would situations—that would be one [714] situation where there is a true, strong relative contraindication to labor induction, and a D&E procedure would be the—medically, the wiser choice, and even common sensically, the wiser choice.

BY MS. KRASNOFF:

Q. Does a woman ever have any underlying medical conditions that would make induction riskier?

A. There are a lot of women who have significant medical problems, and that's one of the reasons that they are having a procedure at this point. And it is not just that they were—the medical problems were just discovered, because there are a lot of women who have medical problems and have worked really hard to plan a pregnancy and try and get a pregnancy to a point where they could continue it. But as the pregnancy progresses, just things are worsening in their medical situation, and they realize it is just not in their best medical interest in consultation with their doctor. So very often, these are very desired pregnancies. In and those situations, if there's severe heart disease or respiratory disease, there are a lot of things about labor induction which, from fluid shifting, from the medicines that you need to give in the very prolonged time course

of an average labor induction that a very short, controlled procedure [715] would be safer for the woman, keeping—I said this yesterday. An operating room is like an intensive care unit in that sense.

I would much rather have a procedure performed medically, in my opinion, perform a procedure under very controlled circumstance, given all of her medical issues, than to have a prolonged process where I can't even guarantee when and if it will be successful.

Q. And what are the complications that go with induction abortion?

A. Bleeding, bleeding significantly enough to require transfusion. The bleeding can occur from abruption, as we talked about yesterday, infection, cervical injury, uterine injury. We are making the uterus contract at a time when it doesn't want to contract.

So we have to give very high doses of medicines, much higher than you would give at term, just because we are trying to override the fact that the uterus doesn't want to do this process. So you have to make the uterus contract so strongly that it can just break apart, to put it in simplistic terms.

And failure of the induction method, inability to successfully complete an induction. And then, retained tissue requiring a surgical intervention, anyway, anywhere from 20 to 70 percent, depending on the study and the methodology used.

Q. When you say "retained tissue," can that be a retained [716] placenta?

A. Primarily it is a retained placenta.

Q. And what percentage again?

A. It can vary from 20 to 70 percent, depending on the methodology. You can look at studies that say:

"In our situation, this is what we found."

But especially with the more modern techniques, the studies are incredibly small. So you have to, just like I mentioned with the studies earlier with incompetence that they are small, but it is the best we have, and we have to look at them for what they are worth.

Same thing with the modern abortion or modern labor induction abortion techniques. The study sizes are incredibly small. So when you look at the percentages of women who had retained placenta and needed intervention, you have to look at that within the realm of: they are small studies, so it can have a wider range.

Q. When you say "need intervention," what does that mean?

A. Usually a procedure like the D&E, just to remove the placenta, because the placenta rarely can fit through a suction cannula. At that point, you really have to—if it is at 20 weeks, you would have to grasp with a grasping instrument the same way to remove the placenta. So it is too large to fit through a suction cannula.

Q. What is DIC?

[717]

A. DIC is disseminated intravascular coagulopathy, which means it's words. It's not just letters. But it's a situation where most commonly because of prolonged bleeding or heavy bleeding that is going on for a long period of time, that the body is not only losing blood cells, but it's also losing the clotting factors that are in

the blood. And the liver can only make these clotting factors so quickly.

So when there is a lot of bleeding over a shorter, prolonged period of time, the body no longer is able to clot. And there is a normal balance that we all have between clotting and not clotting. It goes on all the time in our body. And DIC is the situation where you've lost the balance. You've lost the race.

Q. Do you have an opinion on whether a surgical abortion after, say, 16 weeks versus a labor induction carries a greater risk of DIC?

A. I think over all both of them have an incredibly low risk. If I had to say which one would be greater, in my opinion it would be that the labor induction would have the greater risk just because it is a more prolonged procedure, bleeding over a longer period of time. DIC is, again, just incredibly rare in a very short, controlled surgical procedure.

Q. In your opinion, Dr. Creinin, have there been improvements in the medications used to induce induction abortions in the [718] past 20 years?

A. Not significant improvements at all.

Q. Have the complications that we went over, have those changed in the past 20 years?

A. Not significantly, based on the studies that are available.

Q. And is your testimony about induction based in part on the research you did in order to prepare your book chapter?

A. Primarily, along with discussions with my co-author. One of the reasons that I decided to co-author

the update rather than just do it myself was that Dr. Goldberg, who is my co-author, has a lot more extensive experience with misoprostol, the methods that many individuals choose to use for induction.

And so we decided to do this together. And we both Came to the conclusion that the data that's available compared to the data from decades ago, 10, 15 years ago, methods that were used before that, that there really isn't much proven difference. Nothing that is better. It doesn't mean that it is bad method, but there is just nothing that is better.

Q. Based on that medical literature, specifically, what is your conclusion about the relative safety of surgical abortions as they are performed today and inductions as they are performed today?

A. Based on the literature, I think they're equally safe. I [719] have—I think there is a lot of trends towards more safety with D&E. But, again, that data has to be taken within the realm of how conclusive one can be by looking at the data.

I think there's some recent publications looking at mortality from the CDC, that show that there's no difference in mortality, but a significant trend towards less with D&E. But the statistics, the sample size doesn't allow you to say there is a big difference. And I think all of the literature is pretty similar in that realm, that one is not better, necessarily, than the other. But there are significant trends towards D&E being better. And I think that a lot of it comes down to individual circumstances. And there are definitely medical circumstances and personal circumstances where one procedure, like a D&E, would be obviously preferable. And I would want—I think to best serve my patients, I

would need to provide her with the options that would be best in that individual's circumstance.

Q. Are there any particular studies that you have relied on comparing the modern methods of surgical versus induction abortions?

A. There is not a lot of studies at this gestational age range. But the only one that's—

Q. What gestational age range?

A. I'm sorry. Beyond 18 weeks, 18 to 24 weeks.

[720]

There is one study by Autry, et al, that is a comparative study, and it's probably the best thing we have to look at the issue.

MS. KRASNOFF: That is learned treatise five. If I may I approach, Your Honor?

THE COURT: Yes.

BY MS. KRASNOFF:

Q. Dr. Creinin, I have handed you learned treatise five, which is an article by Dr. Autry, and others, which is entitled:

> "Comparison of Medical Induction and Dilation and Evacuation for Second-Trimester Abortion," published in Volume 187 of the American Journal of Obstetrics and Gynecology, in 2002. Are you familiar with that study?

A. Yes, I am.

Q. And what methods of abortion was it comparing?

A. This study compared labor induction methods versus dilation and evacuation for abortion between 14

and 24 weeks of pregnancy. And the most commonly used medical abortion regime was a misoprostol regime. Not all of the women had that method used. But I believe it was the vast majority, 75 percent, roughly. I would have to look for clarification, but I believe it was 75 percent had misoprostol inductions.

Q. And that is the same medications that are commonly used today?

[721]

A. Yes.

Q. What conclusions do you draw from the Autry study?

A. When they—when the authors compared D&E versus labor induction abortion with the modern techniques that are used—misoprostol, primarily, and still some others—that the overall complication rate was much lower with D&E versus labor induction.

And those were just overall complications. When you look at severe complications they didn't really talk about those as significantly.

They did—there was a lot of analysis looking at women who had blood loss of more than 500 cc's, spending more time in the hospital, those sorts of things.

But this study tells me D&E appears safer. But to talk about it with conclusiveness, you would—you have to take this within the realm it is a retrospective study. There were a lot of things that were not controlled for.

So it goes along with the idea that I can say:

> "The best data I have available tells me D&E is better."

Q. And are you—

A. But I still have to take it with a grain of salt, saying:

> "But I can't say with 100 percent certainty that it is always better for every person."

Q. Are you aware of any data that demonstrates that after 18 [722] or 20 weeks induction is a better method?

A. Not at all.

Q. In your opinion, how would you decide for any particular patient whether she should have a surgical abortion or an induction?

A. Well, I don't. I am not the one who ultimately makes that decision; the patient is.

Q. Dr. Creinin, do your patients ever ask you if the fetus is able to feel pain?

A. Yes, they do.

Q. And what do you tell them?

A. It's actually relatively a common question. I tell them that the best data that we have available, if you look at all the data, says that fetuses are unable to feel pain in the way that we, as humans, feel pain, until 26 weeks.

Q. What is that data that you are referring to?

A. It's a compilation review by the Royal College of Obstetricians and Gynecologists from 1997.

MS. KRASNOFF: This is learned treatise nine, Your Honor, if I may give it to the witness?

THE COURT: Yes.

MS. CLARK: Your Honor, I just want to raise an objection. I am anticipating that she is going to ask for an opinion about fetal pain, and he wasn't been qualified to opine on fetal pain.

[723]

THE COURT: Is that—

MS. CLARK: I think he can talk about what he says to his patients, but—

MS. KRASNOFF: He is only going to report what he tells to his patients. He is not, in fact, an expert on fetal pain.

THE COURT: Go ahead.

BY MS. KRASNOFF:

Q. Dr. Creinin, this is learned treatise nine, which was published by the Royal College of Obstetricians and Gynecologists, and is called:

"Fetal Awareness: Report of a Working Party," from 1997. Is this the data you are referring to?

A. Yes.

Q. And what is the Royal College of Obstetricians and Gynecologists?

A. That's the group or college of obstetricians and gynecologists in the UK, that is the equivalent of we know as the American College of OB/GYN, or ACOG. American College of OB/GYN or ACOG.

Q. And do you know why this report was prepared?

A. There were actually some questions raised by health care providers, as well as by Parliament, which is like our Congress. I guess I didn't need to say that here.

But just questions raised. There wasn't any dogma [724] that said to the Royal College:

"You need to look at this."

But there were enough questions being raised, both privately amongst the health care providers, and publicly, that the Royal College felt that a learned group of individuals needed to be brought together and form a working party to review the evidence in an unbiased fashion.

Q. And who was in that working party, what kind of specialists?

A. There were fetal and neonatal medicine specialists, anesthesiologists, biologists, neurologists and a theologian and a lawyer.

Q. What did the Royal College working group conclude about fetal pain and the ability of a fetus to feel pain?

A. Can I read from what they said?

Q. Sure.

A. There are two main points.

MS. CLARK: I object. This is beyond what he tells his patients.

THE WITNESS: No, this is—I am sorry.

THE COURT: Yes. And you are not a lawyer, either.

THE WITNESS: No, I am. That's why I apologized.

THE COURT: Okay. Your response? She had objected before about the use of the treatise insofar as he was going to express an opinion on fetal pain. You

indicated he was only [725] going to testify as to what he tells his patients. Now he is reading from a treatise. Where are you going?

MS. KRASNOFF: I would just would like to know based on this document if this is what he relies on and what he tells his patients based on this.

THE COURT: Do you have an objection to that?

MS. CLARK: For that simple question, no.

MS. KRASNOFF: Okay.

THE COURT: All right.

THE WITNESS: This is what I tell—roughly what I tell my patients. I can just tell you what I tell my patients.

BY MS. KRASNOFF:

Q. Yes, sure. Just tell me as if I were a patient.

A. That there are multiple things that are necessary—the simple thing I tell my patients, and then I will tell you when they want to know further detail exactly what the working party found.

But the simple way I tell it to them is that pain is something that we understand as conscious beings, and that pain requires us to not only sense something, but to process it as painful.

And a good way of understanding it is if you or someone you know has had major surgery and has been put under general anesthesia, that you don't feel pain during the surgery. It is only once you wake up from the surgery that you [726] feel the pain. So there has to be a consciousness in order to feel pain. And what the working party found is what I base that on is that you can look at the development of nerve fibers in the

periphery, and you can look at the development of nerves that go up to the brain, but then—

MS. CLARK: I will object. I am not sure if this is what he actually tells his patient or if he's explaining how he forms the decision to tell his patients. I think he can testify as to what he tells his patients, but not why he tells his patients that. That seems to be expert testimony.

THE COURT: I disagree with that, counsel. I think that I am going to allow him to explain to me why he tells his patients what he tells them.

THE WITNESS: So, that the nerves need to also develop that go up to the brain. And then, within the brain itself, there has to be the connections that form for the brain to process this as something painful. And a lot of—and I do have patients that ask me, because they have looked on the internet and heard about studies that have shown that fetuses feel pain. And what a lot of those—virtually all the studies look at are things called autonomic reflexes or automatic reflexes.

And, again, the way I explain that to patients would [727] be if you were in a coma, and I tapped your knee, most people know that the knee reflexes. You hit the knee and the leg pops up. If you were in a coma, you would still have that reflex, because the nerves go from your knee to your spinal cord, and then right back. It is an automatic reflex. It doesn't require processing in your brain to say:

> "I felt pain in my knee, therefore I am going to kick."

It is an automatic reflex. So that in no way says that you felt pain. It is an automatic response. And that is what most of the studies on fetal pain show. So

when patients ask me about what they read, that is what I tell them.

BY MS. KRASNOFF:

Q. And based on what you read, and for your practice only, do you feel you need to do anything different for abortions prior to 24 weeks, based on the issue of fetal pain?

A. I don't feel I need to. And also, when I read in the literature, the working party summarizes—concludes you don't need to, based on all of these things, also.

Q. Dr. Creinin, do you ever utilize a chemical agent to cause fetal demise prior to performing an abortion?

A. No.

Q. And why not?

* * * * *

[Dr. Mitchell Creinin—Cross]

[744] woman?

A. I don't understand what you mean by "significant."

Q. If you increase the number of dilators than what you use, that increase in dilators would increase the level of pain that the woman would experience; is that correct?

A. It could, but not always.

Q. Is it increase in the level of pain one of the reasons why you don't increase the number of dilators?

A. For my patients in my situation, yes.

Q. And more dilators also could cause injury to the woman's cervix; isn't that correct?

A. More of anything can cause injury to anything. That is a given.

Q. So many your answer would be "yes" to that question?

A. It's not—yes, that's because it is an obvious question.

Q. You don't set out to dilate the cervix more in order to increase the likelihood that you will be able to remove the fetus intact; is that correct?

A. In order to remove the fetus completely intact, that's correct.

Q. And it is your opinion that in your hands it is safer for you to perform a D&E abortion involving dismemberment of the fetus than it is to perform an intact D&E?

A. Correct.

Q. Now, you have encountered situations in which you are [745] performing a D&E and the fetus is removed intact except that the head of the fetus gets stuck at the internal cervical os, correct?

A. Correct.

Q. When that has happened you have proceeded with the D&E procedure in one of three ways, correct?

A. If you can tell me the three ways I would be happy to.

Q. One method would be to pull on the baby so that the head breaks off from the rest of the body; is that right?

A. Yes.

Q. And then, you will go inside the uterus with the forceps and remove the head?

A. Correct.

Q. The next method is that you would use scissors to puncture the base of the skull?

A. Correct.

Q. And then, you will stick a suction cannula into the opening and drain the brain tissue, and then you will have the head come out.

A. Did you say "drain the brain tissue"?

Q. Then, you will drain the brain tissue?

A. Yes.

Q. And have the head come through the suction cannula?

A. I am sorry. What was the last thing you said?

Q. And then you would have the head come through the cannula?

[746]

A. No, the head then comes through the cervix.

Q. And the third method is that you take a crushing instrument, phut *[sic]* that instrument inside the cervical os, crush the baby's head, and pull the head through the cervix, correct?

A. That would be the third possible, although physically that would virtually never be the case. It would be one of the first two. Those are my three options, but it would be one of the first two that I could realistically do.

Q. When you have had the head lodge in the cervix, have you performed those three methods for dealing with the head?

A. Just the first two.

Q. From November 1, 2002 through November 1, 2003, you have been presented with patients in which the baby's head got stuck at the internal cervical os approximately five to ten times, correct?

A. Yes.

Q. In your career, you've had this happen approximately 50 times?

A. Yes.

Q. In these situations in the last year where the head got stuck, there is no maternal health condition that caused the head of the fetus to get stuck, correct?

A. That caused the head to get stuck? No. That is part of the abortion procedure.

[747]

Q. There is nothing unique about the fetus that presented the situation?

A. No.

Q. None of the fetuses had hydrocephaly?

A. No.

Q. In your career in approximately five to ten times the cervix has actually been so dilated during a surgical transvaginal abortion that the entire fetus was removed intact with having to collapse the skull. Let me repeat it for the court reporter. In your career in approximately five to ten times, the cervix has actually been dilated so much during a surgical transvaginal

abortion that the entire fetus was removed intact without having to collapse the skull?

A. Correct.

Q. And the fetus was somewhere between 16 and 24 weeks?

A. Correct.

Q. Doctor, if a woman's cervix was so dilated the fetus could be delivered in intact it would not be necessary to collapse the skull because the fetus could pass through the cervix, right?

A. Correct.

Q. But you would not allow the fetus to pass intact if the fetus were at or about 24 weeks in gestation, correct?

A. Correct.

* * * * *

[754]

A. Yes.

Q. Now, doctor, another article that you relied upon in forming your opinions was the Henriet and Kaminski study?

A. Henriet, yes.

Q. Henriet. Henriet. Henriet study, titled:

> "Impact of Induced Abortions on Subsequent pregnancy outcome the 1995 French National Perinatal Survey";

Is that right?

A. Yes.

Q. The study by Henriet supports the opinion that an induced abortion can result in a woman not being able to carry a subsequent pregnancy to term; is that correct?

A. No.

Q. Doctor, I direct your attention to your deposition, page 229.

A. Can I also have the article, since you are talking about it, please?

MS. CLARK: This is defendant's Exhibit lta-29. Your Honor, may I approach?

THE COURT: Yes.

BY MS. CLARK:

Q. Doctor, turning to your deposition testimony, page 229, Line 3, if you would read to yourself three through 12.

A. Yes.

Q. That reads:

[755]

> "Question: And have you read the Henriet and Kaminski study? "Answer: Yes. "And is it your opinion that the study supports the fact that induced abortion can result in a woman not being able to carry a pregnancy to term? "Answer: In my opinion, the results they presented support that. It could effect a woman's ability to bring a pregnancy to term." That was your testimony, right?

MS. KRASNOFF: Your Honor, I object. She didn't read the complete answer to the question.

THE COURT: All right. You may read the complete answer. Now. You may read the complete answer now.

MS. KRASNOFF: Oh, I am sorry. The rest of the answer says: "It is an awful study. You can't make any real basis on that—on the opinion."

THE COURT: Okay. All right.

BY MS. CLARK:

Q. So, doctor, you agree that the study, in fact, supported that an abortion can cause cervical incompetence, right?

A. No. It is an awful study, and you can't make any real [756] basis—

Q. But the study does, in fact, conclude that induced abortion results in cervical incompetence?

A. The study concludes that.

Q. Okay. That study looked at virtually all births over a series of days in France; isn't that correct?

A. Yes.

Q. And the study's population consisted of 12,432 women; isn't that right?

A. Yes.

Q. And in doing that study it asks those women—it asked whether those women previously had had an induced abortion, right?

A. Correct.

Q. And turning your attention to page 1041, under the "conclusions" section, that study states or that conclusion states, and I quote: "A significant association between previous induced abortions and pre-term

delivery in subsequent pregnancies was observed, the risk increasing with the number of previous induced abortions." That was the conclusion, right?

A. Yes.

Q. Now, in forming your opinions today, specifically with * * *.

* * * * *

[Dr. Mitchell Creinin—Redirect]

[780] so you can go by intention to treat, but the real crux of it is this is abortion, patients seeking abortion services, not patients who are seeking a delivery. There are patients who have heart disease that are able to be randomized between a medical treatment and a surgical intervention. But that doesn't mean that we can do that for abortion.

We do have studies that show us within the abortion literature that it's impractical, unfeasible, unreasonable and if—then, we also know the issue of getting funding for such a large study would be unlikely. I don't think—I won't opine on my position of the U.S. government in funding for abortion studies.

Q. That's all right. Now, I'll switch. Ms. Clark asked you about the Henriet study relating to cervical incompetence. And I read your deposition that you think that that is an awful study?

A. Correct.

Q. Is that your opinion?

A. Correct.

Q. If you could take a look at that and explain the basis for your opinion that that is an awful study?

A. Well, the reason I said it was an awful study is that I was being asked about the study in the context of abortions at 18 weeks or greater. And there are a couple of things to keep in [781] mind. First, the study was a study that in a population of women where the abortions that were performed, 96 percent of them were in the first-trimester or in early abortions. And that is because that's—and it is brought out in the article about that is when abortions are performed in France. So—

Q. In fact, if I direct your attention to page 1041.

A. Right. It says—

Q. It says that only 4 percent of women for the study had abortions after 11 weeks gestational age?

A. Correct. So it is not relevant to what we are talking about. It is a different group of women. And then, when you look at the issue of cervical—well, more specifically about the study, it was also a retrospective study that asked women who had a delivery: "Can you tell us about what happened in the past?" And recall bias is so strong in studies of that nature. I mean, a great example—

Q. Can you explain what "recall bias" is?

A. Recall bias is when you ask somebody about what happened to them in the past. They are more likely to recall everything if they had a bad outcome and not recall everything if they have not had a bad outcome, because they are looking for you to help [782] them explain why they had their bad outcome.

A great example is the breast cancer and abortion literature. The National Cancer Institute came out with a large—with a review of all of the literature

saying there is no relationship between abortion and breast cancer.

There are some studies in the literature that have suggested that, and they are just filled with recall bias, because if you had breast cancer or any other—not you, specifically—a woman had breast cancer, I apologize—and I came to her saying:

> "I am doing a study and trying to figure out why you might have had breast cancer. Tell me, did you have eat fish? Did you ever have an abortion? Did you ever do X, Y or Z?"

She is much more likely trying to spend a lot of time trying to remember all the details than she would if you had just said:

> "You are a healthy person. Can you tell me about all of those things?"

And they are also less likely to admit it. And that is very well-established in the medical literature about the problems with recall bias.

So when you add that to the fact that this is primarily first-trimester patients, it doesn't have any relevance.

[783]

The other issue is that when you are looking at a woman facing an abortion between 18 and 24 weeks, you have to have the appropriate comparator. This is looking at the risk of subsequent pregnancy outcome based on women who had an abortion in the past. The other option was to not have an abortion, and that is, in a sense, the comparison. If we are taking a woman who between 18 and 24 weeks is facing—is looking at having an abortion and she's deciding between method, that is

not comparing it to not having an abortion. It is comparing the two methods. So this study is no way is relevant to the discussion we are having. Did I make—

THE COURT: I understand.

THE WITNESS: Okay.

BY MS. KRASNOFF:

Q. And, finally, there's one more study. This is a study of pre-term delivery. Is pre-term delivery the same thing as cervical incompetence?

A. No, not at all. Cervical incompetence is painless dilation of the cervix which can result in pre-term delivery. But the majority of pre-term deliveries is from pre-term labor, which is a separate entity.

So you can't bundle them into one entity when, in fact, the vast majority of pre-term deliveries in our country [784] are related to pre-term birth, and rarely cervical incompetence.

Q. You were discussing multiple passes versus intact. Is one category of procedure where you remove the fetus completely intact without having to take or to compress the head?

A. Correct.

Q. A different category which you were calling intact D&E, is where you removed the fetus up to the calvarium, and you use a scissors and suction to remove the fetus; is that correct?

* * * * *

[785]

A. Scissors to puncture the skull to drain, right. Correct.

Q. The third category which I think you called a D&E, you may remove the fetus up to the point of the aftercoming head, but then disarticulate further. That would be a D&E?

A. Correct, and any of the—

THE COURT: I didn't under the distinction between the second and third.

MS. KRASNOFF: He's—

THE COURT: Second and third category.

MS. KRASNOFF: Oh, the second was specifically using a scissors to pierce the base of the skull and the suction instrument to remove the intracranial contents.

THE COURT: Okay. The third was—

MS. KRASNOFF: The cranium lodges and uses disarticulation to remove the fetal trunk, and then remove the skull, thereafter.

THE COURT: All right. And, Doctor, the category in which you described three prior experiences, was that in the first category or the second category?

THE WITNESS: Second.

THE COURT: The second category?

THE WITNESS: The second was intact. That is what is medically called an intact D&E procedure.

THE COURT: Okay. And you have not had any experience with the first category?

[786]

THE WITNESS: No.

BY MS. KRASNOFF:

Q. You took out one, two and three.

A. The first category being that the fetus comes out completely intact?

THE COURT: Right.

THE WITNESS: There have been situations, most commonly if there is a multiple pregnancy and the first one is removed by D&E, and then the second one because the cervix is very pliable at that point will come out completely intact.

THE COURT: Have you had that experience?

THE WITNESS: Yes. In all of those situations, though, regardless of whether the fetus comes out completely intact, intact up to the head, and I do a procedure on the base of the skull, or I dis—or it comes out completely at the level of the head, and I disarticulate it, all of those have at times gone intact or relatively intact to the level of the umbilicus or greater and would violate the law.

THE COURT: Okay.

BY MS. KRASNOFF:

Q. And do you know at the outset whether it is going to be one of those three?

A. No.

Q. I think you testified about this on direct a little bit. Why do you in the abortions you do not seek to get more * * *.

* * * * *

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

No. 4:03CV8695 (RCC)

NATIONAL ABORTION FEDERATION, MARK I. EVANS, MD, CAROLINE WESTHOFF, MD, MSC; CASSING HAMMOND, MD, MARC HELLER, MD, TIMOTHY R.B. JOHNSON, MD STEHEN CHASEN, MD, GERSON WEISS, MD, ON BEHALF OF THEMSELVES AND THEIR PATIENTS THEY SERVE, PLAINTIFFS

v.

JOHN ASHCROFT, IN HIS OFFICIAL CAPACITY AS ATTORNEY GENERAL OF THE U.S., ALONG WITH HIS OFFICERS, AGENTS, SERVANT, EMPLOYEES, AND SUCCESSORS IN OFFICE, DEFENDANTS

Apr. 5, 2004

9:00 a.m.

APPEARANCES

AMERICAN CIVIL LIBERTIES UNION FOUNDATION
Attorneys for Plaintiffs

125 Broad Street, 18th Floor
New York, New York 10004-2400
(212) 549-2600

BY: DIANA KASDAN, ESQ.
JULIE STERNBERG, ESQ.

THE ROGER BALDWIN FOUNDATION OF
THE ACLU, INC.
Attorneys for Plaintiffs

180 N. Michigan Avenue, Suite 2300
Chicago, Illinois 60601
(312) 201-9740

BY: LORIE A. CHAITEN, ESQ.

WILMER CUTLER PICKERING LLP
Attorneys for Plaintiffs

2445 M Street, N.W.
Washington, D.C. 20037-14
(202) 663-6235

BY: A. STEPHEN HUT, JR.
AMY WIGMORE, ESQ.
KIMBERLY A. PARKER, ESQ.

SHEILA M. GOWAN, ESQ.
SEAN H. LANE, ESQ.
JOSEPH A. PANTOJA, ESQ.
ELIZABETH WOLSTEIN, ESQ.
Attorneys for Defendants

U.S. Department of Justice
86 Chambers Street, 3rd Floor
New York, New York 10007
(212) 637-2800

* * * * *

[Dr. Marilynn Frederiksen—Direct]

[1045]

A. Yes.

Q. Briefly explain what that term means as you understand it.

A. It is a procedure by which you use serial laminaria in the cervix over a period of time, after which there is adequate dilatation to allow extraction of the fetus relatively intact.

Q. Can you also assure that the fetus will be removed intact?

A. No, I can't.

Q. Why is that?

A. During the process of doing those techniques, you may encounter resistance to the cervix. The fetal tissues are relatively fragile, and you can't guarantee getting the fetus out totally intact.

Q. Do you ever perform a D&E using the intact approach?

A. Yes.

Q. Do you do those as part of your regular practice?

A. Since my training in the seventies, I have gradually changed the protocol under which I operate and have found that when I can get the fetus out relatively intact, I can ensure that there is no retained fetal tissue within the uterus, decreasing the risk of infection. The procedures are generally shorter, and the blood loss and the anesthesia time is less for the woman, so that it is a safer procedure.

Q. Approximately how many times have you performed an intact D&E?

A. I don't know.

* * * * *

[1052]

Q. When you say "midtrimester," what are you referring to?

A. It is generally referred to as 13 to 28 weeks, although we don't go beyond 24 weeks in the termination of pregnancies.

Q. Dr. Frederiksen, on what do you base your opinion about the safety of D&E in the midtrimester, aside from the publication you have just mentioned?

A. There are other publications. There was a whole series of them by David Grimes talking about the safety of the D&E. They generally supported the safety to about 20 weeks. Beyond that, it is really an individual basis of the individual operator.

We did a study at Northwestern that was prompted by a paper in the American Journal of Obstetrics and Gynecology by Chapman that showed that there was about a 2.3 times higher risk of uterine rupture and hemorrhage with patients who had had a prior Cesarean section undergoing second trimester pregnancy termination by induction. All of their patients were induced.

It has not been our experience at Northwestern that we felt that those patients were at any higher risk, nor did we experience any increase in hemorrhage from patients who had had a prior Cesarean section. So we opened a study under IRB guidance that looked at a 5-

year period of time, which we looked at our experience. Our definition was 13 to 24 weeks of gestation, and we compared not only inductions but D&E's. D&E's were not part of the Chapman paper.

[1053]

We showed that there was no increased risk to a patient that had a Cesarean section. But the most striking difference between our data showed that the induction method was significantly more risky for a patient and that D&E was significantly more safer, and that did include patients to 24 weeks.

Q. Dr. Frederiksen, does your opinion regarding the safety of second trimester D&E procedures include an approach that would be the intact approach to D&E?

A. Yes.

Q. Do you have an opinion as to whether intact D&E is ever safer than other abortion procedures?

A. An intact D&E is always safer because the fetus comes out relatively intact, involving less passes of the instruments into the uterus. It also has no ability to leave fetal parts within the uterus. There are less bony parts or bony fragments which can lacerate or cut the cervix as they are delivered from the uterus. And there is less blood loss overall.

Because the procedure is with the intact delivery of the fetus, the placenta usually delivers intact as well.

Q. What do you base that opinion on?

A. My experience and the—well, the majority of it is my experience.

Q. Do you also base it on the medical literature that you have been referring to?

[1054]

A. The medical literature doesn't do a specific study on intact D&E's versus classical D&E's, and there hasn't been any study in that area. But embedded in the D&E data over the last 10, 15 years, there are more and more operators that have moved from doing a strictly dismemberment procedure to an intact variation. So it is embedded in that. And we have shown that D&E has become much more safer as time has gone by.

THE COURT: Doctor, what is an operator?

THE WITNESS: The person doing the procedure.

THE COURT: You don't call them a doctor?

THE WITNESS: Yes, you can call them a physician.

THE COURT: But you choose "operator"? Are they all physicians?

THE WITNESS: Yes.

Q. Do you use the term "operator" when you are referring to somebody who is doing an operation?

A. Yes.

Q. Or in other contexts?

A. No. Just in terms of doing operations, a person is operating.

Q. So it would be the physician doing an operation?

A. Correct.

Q. Thank you. Dr. Frederiksen, you have testified that you have performed the intact variation of D&E, is that correct?

A. Yes.

[1055]

Q. Why do you use that approach?

A. Because overall it is safer for the pregnant patient.

Q. You have mentioned a number of reasons why you believe that it is safe, and I would like to break that down and take then one by one and ask you some more questions about them. First, you mentioned that there are fewer passes with instruments. Why is this a safety advantage?

A. When you are passing instruments into the uterus, you always have the ability to inadvertently go through the wall of the uterus and perforate the uterus and deliver something that you don't intend to deliver. That could include maternal tissues.

Q. Is that something of concern to you?

A. Uterine perforation is a medical emergency. A bowel injury or an injury to maternal tissues is also an emergency, mandating exploration of the maternal abdomen to repair damage.

Q. When you refer to a bowel injury, is that something that can result from a uterine perforation?

A. Yes.

THE COURT: Have you ever perforated a uterus or done any of these things?

THE WITNESS: Yes.

THE COURT: Were you ever sued for malpractice?

THE WITNESS: Yes.

THE COURT: Involving an abortion?

[1056]

THE WITNESS: Yes.

Q. Have you ever perforated the uterus using the intact approach to D&E?

A. No.

Q. Doctor, how is it that you are —

THE COURT: Just one second. In the malpractice suit against you, Doctor, did the plaintiff recover?

THE WITNESS: No.

THE COURT: Was there settlement?

THE WITNESS: No. We won.

MS. CHAITEN: May I inquire, your Honor?

THE COURT: Sure.

MS. CHAITEN: Thank you.

Q. Dr. Frederiksen, how is it that uterine perforation occurs during a D&E in the second trimester?

A. Perforation is much more common with forcible dilatation of the uterus, but it can be an inadvertently happened when you are using forceps to grab tissue. There can be irregularities in the uterine wall which make you think there are fetal parts there and there are not. There can be irregularities in the thickness of the uterine wall, including with a scarred uterus, where you can very easily go through the scar, the prior scar, or have the scar open, and you then have a chance of delivering anything from the maternal abdomen.

Q. Doctor, you mentioned that uterine perforation is more [1057] common with forcible dilatation of the uterus. What is forcible dilatation of the uterus?

A. Forcible dilatation of the cervix is a gradual p[illegible]s by which you use metal dilators to introduce t[illegible] into the uterus and essentially force them through the uterus. That can cause damage to the cervix.

Q. Do you use forcible dilatation in any second trimester intact—I'm sorry. Let me rephrase.

Do you ever use forcible dilatation in a second trimester D&E procedure?

A. I do not.

Q. Doctor, is there a high risk of uterine perforation from repeated instrumentation of the uterus during a second trimester D&E?

A. The more passes that you do, there is a chance for passing those instruments through the uterus.

Q. But is it a significant risk of that happening? Is there a high risk of that happening?

A. In the second trimester, because we use cervical dilators, cervical dilatation by laminaria or misoprostol, it is less frequent than with a first trimester termination. But it still can occur.

THE COURT: Does that translate that it is a low risk, Doctor?

THE WITNESS: It is low risk in occurrence, yes.

[1058]

THE COURT: Thank you.

Q. Then why are you concerned about it?

A. Because it is a medical emergency and places the patient at the necessity of doing a subsequent abdominal operation to explore damage.

THE COURT: That is if it happens?

THE WITNESS: Correct.

THE COURT: But it is a low risk event. Next question.

Q. Doctor, you also testified that intact D&E can reduce the risk of cervical laceration. Why is that?

A. Cervical laceration can actually nick an internal branch of the cervical artery as well as lacerate the endocervical canal and cause bleeding. The leading cause for this is bony pieces, pieces of bony parts of the fetus which can be very sharp, and when you pull them through the cervix can lacerate the cervix and cause hemorrhage.

Q. What causes the presence of sharp bony parts in the first place?

A. The dismemberment process that is necessary to empty the uterus.

Q. Are these fragments present in an intact evacuation?

A. No, they are not.

Q. Why not?

A. Because the fetus is delivered almost or virtually intact, [1059] and thereby you don't have those bony fragments.

Q. Dr. Frederiksen, is there a high risk of cervical laceration or uterine perforation from bony fragments during a D&E?

A. If you end up having a situation where you end up having multiple fetal parts, there is always a risk of cervical laceration.

Q. Is that why you try to control for this risk?

A. We decrease that risk by doing an intact or near intact procedure.

Q. Doctor, you mentioned in the case of uterine perforation, as well as in the case of cervical laceration, that it could require an additional procedure, is that correct?

A. Yes.

Q. Would the additional procedure that is required be riskier than a second trimester D&E?

A. Absolutely.

Q. Why is that?

A. When you open the abdomen, you are increasing the risk of infection, wound infection, and you don't know what you are going to encounter. It can be a bowel injury, it can be bowel spillage. It can be just a uterine perforation or it can be involving damage to the ovaries and tubes as well. So it depends upon what the extent of the damage is.

You also can get hemorrhage or delayed hemorrhage from [1060] perforations, and the hemorrhage can be into a space behind the abdominal cavity which can accommodate quite large amount of blood without being noticed.

Q. Doctor, you mentioned opening the maternal abdomen. Is that part of the subsequent procedures that are necessitated by cervical laceration or uterine perforation?

A. Yes.

Q. You testified that intact D&E can also produce the risk that fetal tissue or parts can remain behind in the uterus. How is it that fetal tissue or parts can remain behind doing an D&E?

A. If you do a D&E where the fetus doesn't come out intact, you are making an assumption or you make your best clinical estimation that the uterus is entirely empty. Unfortunately, we are not very good at that, and we can leave either fragments of the fetus in the uterus or fragments of the placenta in the uterus, and there can be a nidus for infection and there can be the cause of a post-abortal hemorrhage.

Q. Used the word "a nidus." What is that?

A. Like a focus.

Q. So it would be a location of, a point of infection?

A. Yes.

Q. What is post-abortal hemorrhage?

A. Post-abortal hemorrhage is hemorrhage which occurs after the abortion has occurred. It can be episodic or you can get a [1061] hemorrhage and then find no evidence for the bleeding by examining the patient. That is characteristic of a cervical artery laceration of the internal os or the internal os of the cervix, where bony fragments can lacerate that branch of the cervical artery.

Or they can be caused by the uterus failing to contract or maintain a contraction after the delivery of the fetus and the majority of the pregnancy. That is called uterine atony, and that may necessitate reexploration of the uterus or use of medications.

Q. Why are you concerned about the uterus failing to contract? What purpose does that serve?

A. The physiological changes of pregnancy increase the cardiac output proportion that goes to the uterus during pregnancy. That is maintained in the post-partum stage. So an obstetrical post-partum hemorrhage or a post-abortal hemorrhage—

THE COURT: Doctor, can you slow down a little bit? The reporter has to get it all.

THE WITNESS: Yes.

A. I don't know where I was.

Q. I had asked you about why you were concerned about the uterus being able to contract after an abortion procedure.

A. During pregnancy a higher proportion of the cardiac output is directed to the uterus, and that is maintained in the post-pregnancy termination period, whether that be at 24 weeks * * *.

* * * * *

[1067] a percent of midtrimester terminations.

The safety for women for terminating pregnancy in the midtrimester actually has gone up as best evidenced by the paper that just came out where that's one of the points that the authors make, that as D&E has gotten safer, that induction procedures have not been used and their relative safety is less than a D&E.

Q. Why do you believe induction is riskier?

A. It's taking a patient in the midtrimester whose uterus is not really ready for labor and attempting to

put the uterus and cervix into labor and delivering the fetus.

The whole process takes a long time because the cervix is not ready to dilate and the uterus is really not ready to contract.

The pharmacological mechanisms by which we have done this over a period of time have been prostaglandins instilled into the amniotic fluid, prostaglandins that are injected, and we used to use suppositories of prostaglandin in the vagina. We now use another form of prostaglandins in the vagina that seems to be the safest way that we can do this, but the whole period of time that takes a patient to go from a cervix which is long and closed to shortened and dilated can be nine, 14, 24, 36, 48 hours. It's an open-ended period of time.

It also associates the uterus and the contents of the uterus to anything that's in the vagina and we know that [1068] infections originate from vaginal flora that ascend into the uterus increasing the risk of infection.

There is also a risk of hemorrhage at the time or during the process. It's a long painful procedure for the patients. It's essentially analogous to labor and there really is not anything that they're going to deliver other than a fetus, which they are choosing to terminate.

Q. How does that compare to a D&E?

A. The D&E procedure begins with dilating the cervix with laminaria which are seaweed twigs placed in the cervix which absorb water from the mother's body then gradually begin the process of softening the uterus and dilating the os or the opening of the cervix to the gradually over a process of time.

We also use misoprostol orally or vaginally to facilitate this process; that's lower dose medications than what we use for induction of a midtrimester termination.

And then we bring the patient to the operating room and can empty the uterus under a controlled period of time and thereby have a controlled handling of the placenta and ensuring that the uterus is empty. We can also decrease the total time the patient needs to be away from her family and other children or a job and there is less pain for her because she doesn't go through labor.

Pain has become a major issue with respect to how we handle midtrimester terminations and now we are actually giving [1069] patients epidural anesthetics for the conduct of midtrimester pregnancy terminations.

THE COURT: Doctor, do you make full disclosure to all your patients before you embark on a particular procedure?

THE WITNESS: I educate them in the process of an informed consent as to the risks of pregnancy termination and the relative difference of risks of the different procedures.

THE COURT: Well, when you tell them about pain and such that you were talking about before, do you also tell them about that you do the D&E, it involves dismemberment? Do you tell them that you tear the limbs off the fetus?

THE WITNESS: I don't use that term, as I say it.

THE COURT: Do you use simple English words so they know what you are doing—

THE WITNESS: Yes.

THE COURT: —and what they're authorizing?

THE WITNESS: Yes.

THE COURT: Well, how do you tell them that you are going to take the limb off?

THE WITNESS: I tell them that in the process.

THE COURT: Do you use "disarticulation"?

THE WITNESS: No.

THE COURT: What word do you use?

THE WITNESS: I tell them that in the process of the termination we will attempt to get the fetus out as intact as * * *.

* * * * *

[1077] procedure.

Q. Do you consider the failure of the placenta to deliver during a second trimester induction procedure a complication?

A. Yes.

Q. Why is that?

A. Because it entails another procedure to end the whole pregnancy termination process.

Q. Doctor, does an induction termination always work—

A. No, it does not—

Q. —I'm sorry—to expel the fetus?

A. No, it does not.

Q. What happens in that situation?

A. Often times there is enough cervical dilatation and softening that we can go ahead with the dilatation and evacuation.

If you do not have access to an operator that has skills with D&E and you have a failed induction, the only other option would be a hysterotomy.

Q. What is a hysterotomy?

A. Hysterotomy is abdominal incision through the abdominal wall into the uterus and into the uterus for purposes of emptying the uterus.

Q. So you cut open the maternal abdomen?

A. Yes; and the uterus. And the incision on the uterus is usually a vertical * * *

* * * * *

[Apr. 6, 2004]

[1139]

Q. Doctor Frederiksen, yesterday, when we were speaking, when you were testifying, you mentioned a patient with a prior uterine scar. What procedure would you want to do for a woman with a uterine scar?

A. A D&E or intact variation thereof.

Q. Doctor, is there ever a clinical reason that you would choose a dismemberment procedure for a particular patient as opposed to trying to remove the fetus as intact as possible?

A. No. The specific clinical situations are usually that an intact variation of a D&E is safer. There may be a rare case where you would have a conjoined twin where dismemberment wouldn't be necessary to

deliver the fetus, but even in that situation you would want to deliver the fetus as intact as possible.

Q. Doctor, if the fetal head gets stuck in the cervix in a second trimester D&E, is it possible for the fetal body past the level of the navel to be outside the body of the woman?

A. Yes.

Q. How does that work?

A. There is a holder on the cervix, I usually use a ring forcep for this, and the traction on the uterus may deliver the cervix to the level of the entrance to the vagina. Moreover, you actually can have a particular patient with a prolapse of the uterus undergoing a procedure and her cervix can actually be outside of the body.

[1140]

Q. Doctor, do you do anything different when dilating for an intact approach to D&E than for any other D&E?

A. No, I do not.

Q. Doctor, have you ever injured a patient in the process of using scissors to make an incision in the base of the fetal head during an intact D&E?

A. No, I have not.

Q. Are you aware of any other physicians who have?

A. No.

Q. Is it always necessary to make an incision at the base of the fetal head to facilitate delivery in an intact D&E?

A. No, it is not.

Q. Why not?

A. In certain circumstances it is easier to just use grasping forceps and deliver the head through the cervix.

Q. Dr. Frederiksen —

THE COURT: Excuse me. Grasping forceps, does that mean you crush the skull?

THE WITNESS: You compress the skull, yes.

THE COURT: You crush it, right?

THE WITNESS: Yes.

THE COURT: Yesterday you mentioned sometimes you use your finger, right, rather than using scissors?

THE WITNESS: No, that is not my testimony.

THE COURT: Isn't that what you said?

[1141]

THE WITNESS: No, that is not. I said the scissors would be important to make an incision at the base of the skull, but I don't use suction. I use my finger to disrupt the contents of the cranial cavity, to thereby collapse the skull and allow delivery of the fetus.

THE COURT: So you use your finger to get the contents of the skull out rather than sucking the contents of the skull out, is that correct?

THE WITNESS: Yes.

THE COURT: Next question.

Q. Do you actually remove the contents of the skull, Doctor?

A. Not necessarily.

Q. Dr. Frederiksen, you testified yesterday about the general safety advantages of an intact to D&E. Do you have an opinion regarding whether an intact approach to D&E offers particular safety advantages for women with certain medical conditions?

A. I do.

Q. What is that opinion?

A. Women with certain medical conditions are sometimes better served by intact D&E than any other method of intact termination because the fetus comes out as intact as possible with less lacerations to the cervix and less chance of prolonged procedure, hemorrhage, or of tissue left within the uterus, thereby providing a nidus for infection.

Q. Can you give some examples of particular medical conditions [1142] for which an intact D&E would offer additional safety advantages?

A. Acute fatty liver of pregnancy, sepsis, where you have an unstable patient and significant infection within the uterus. Those are two that come to mind.

Q. Let's talk first about sepsis. Why would an intact approach to D&E offer particular advantages for a woman at risk for sepsis?

A. A patient who is septic, and the particular circumstances is not only that there is chorioamnionitis, or an infection in the uterus, but there is infection in the uterus, she can be hemodynamically unstable or in shock with low blood pressure, high pulse, and potential of metabolic acidosis injuring the lungs.

THE COURT: Doctor, going back to hemo, what was the term?

THE WITNESS: Hemodynamic.

THE COURT: Do you want to define these terms? You get talking in very technical terms. We aren't going to understand it.

THE WITNESS: Hemodynamics is the function of the cardiovascular system that maintains pulse and blood pressure. In a patient in septic shock, you have very, very low blood pressure and a very high pulse. That lack of cardiac output decreases blood to the kidneys, to the lungs, and to other [1143] maternal tissues. In that situation, you can have the development of metabolic acidosis.

THE COURT: What is that?

THE WITNESS: That is a change in pH.

THE COURT: What is that?

THE WITNESS: The acid/base balance. Is that sufficient?

THE COURT: What does that mean?

THE WITNESS: Acid/base is the amount of acid or base that is in the maternal bloodstream. It is usually kept in a very, very tight range physiologically. When you do not have adequate profusion of maternal tissues, the maternal tissues continue to make acid and waste products and they cannot be gotten rid of by the normal physiologic processes. Therefore, you get the development of more acids in the bloodstream. With that, you can also develop what is called disseminated intravascular coagulation. That is a process by which you consume the clotting factors in the bloodstream as

well as is the platelets. Platelets are small, subcellular elements of the clotting system which are usually the first mechanism by which the body stops blood loss in capillaries or in vessels. In a situation with metabolic acidosis, you also have the development of disseminated intravascular coagulation, a consuming of the clotting mechanism. Therefore, the patient is [1144] at increased risk for hemorrhage. When you have a patient who is at increased risk for a hemorrhage, an intact D&E would be the optimal way to empty the uterus, because you would decrease the chances that the cervix would be lacerated during the process of delivery of the fetus.

You also decrease the risk of hemorrhage, and hemorrhage in the second trimester is the highest cause of complications.

Q. Does it affect the procedure time, Doctor?

A. Procedure times for second trimester terminations with an intact or near intact delivery of the fetus are actually shorter.

Q. Than for a procedure with more dismemberment?

A. That's correct.

Q. Could you do an induction for such a patient who is at risk for sepsis?

A. An induction is possible, but, again, we are taking the patient through a riskier procedure and a longer procedure.

THE COURT: Longer for you, too, isn't it, Doctor?

THE WITNESS: Yes. But my focus is really on getting the patient delivered in a situation where she has the potential of multiorgan system failure and death.

THE COURT: But it is for a time of yours, which means less time for other patients, right?

THE WITNESS: If I have a patient in septic shock, I don't have the ability to take care of any other patient while [1145] I am taking care of that patient.

THE COURT: But also, if you do this procedure rather than induction, it takes more of your time, therefore you can devote less time to other patients, correct?

THE WITNESS: Actually, an induction may not take as much time, because the induction process has actually begun and the whole length of time that the patient is undergoing induction I may be doing other things.

Q. Doctor, you said that if you have a patient in septic shock, you are not treating other patients. Is that regardless of what type of procedure you are using the terminate the pregnancy?

A. Yes.

Q. You also mentioned something called acute fatty liver of pregnancy, is that correct?

A. Yes.

Q. What is that?

A. Acute fatty liver of pregnancy is caused by the fetus having an inborn error of metabolism of long-change fatty acids. Long-chain fatty acids were the structural molecules by which many of our cell

membranes and other fats are stored within the body. If the fetus cannot metabolize long-chain fatty acids, they can accumulate in the meantime and be then transferred to the maternal cardiovascular system for excretion. In acute fatty liver pregnancy, the biopsy of a [1146] liver will show that there are lengths of fatty acids within the liver deposits and they are really coming from the fetus.

Q. Whose liver are you referring to?

A. I'm talking about the mother's, because that is the person who has acute fatty liver of pregnancy.

Q. So it is something that comes from the fetus that makes the pregnant woman ill?

A. Yes. The fetus and the placenta. Because the placenta has the same genetic endowment as the fetus, thereby it is the placenta that probably does not metabolize long-chain fatty acids in a normal fashion, giving increased levels of long-chain fatty acids to the mother, which she also cannot clear.

Q. What is the result of her inability to clear those long-chain fatty acids?

A. She develops hepatic failure or liver failure.

Q. Why would an intact approach to D&E offer particular advantages for a woman suffering from acute fatty liver of pregnancy?

A. These patients can be very sick. They can develop not only liver failure, but because of a liver failure they can develop renal failure or kidney failure. In that situation the liver is the principal place of production of all of the clotting factors that I mentioned earlier. When the liver is not functioning, the patient then has less proteins within their bloodstream to clot

blood. They [1147] can also, again, consume platelets and be in a situation where they are in disseminating intravascular coagulation or with a very low platelet count, as well as low concentrations of the clotting proteins within the bloodstream.

Q. Could you do an induction for such a patient?

A. Yes. But, again, it is long. And the patients, because they are very, very sick, a longer procedure actually presents an increase risk for continued renal failure as well.

THE COURT: Have some women gone to full term with that condition?

THE WITNESS: Yes. It can develop over an acute period of time. It can be in the second trimester or in the third trimester. But there is really no therapy other than ending the pregnancy.

THE COURT: But some have gone to full term and delivered the baby?

THE WITNESS: Not after they develop acute fatty liver pregnancy. They are developing acute fatty liver pregnancy in the third trimester, and if they develop at that point, we can deliver the fetus in a safe manner and treat both mother and baby.

THE COURT: But it could be life threatening then, too, if it gets to that stage, correct?

THE WITNESS: Yes. It is a matter of when it presents.

[1148]

THE COURT: Next question.

Q. Doctor, are any of the conditions you have mentioned ones that could lead to the need for termination on an emergency basis?

A. Yes.

Q. How would you achieve adequate dilation on an emergency basis in order to perform a D&E, including the intact variation?

A. We can use laminaria and misoprostol.

Q. But you wouldn't have the ability to do that over a 24-hour period, is that correct?

A. You can start an induction and have the patient develop acute deterioration. I have been in situations where particular patients have had an induction begun and it has taken 24 or 36 hours, and during that process they have developed—I use a large term —hemodynamic instability or septic shock. At that point we usually intervene to end the process as quickly as possible, because it is life-threatening to the mother.

Q. What if it is a situation where you are not attempting to convert from an induction, you have a patient who presents with a particular medical condition who needs to terminate the pregnancy on an emergency basis. How would you go about achieving adequate dilation?

A. It would depend upon the gestational age. In a hospital [1149] situation we have the ability to add laminaria and treat the mother with vaginal misoprostol alternatively—alternatingly, and achieve enough dilatation so that we can on a short period of time—by short, I mean less than it would take to do an induction—get the patient adequately dilated and allow for delivery of the fetus.

Q. Doctor, can one take steps to assure fetal demise prior to initiating a D&E in the second trimester of pregnancy?

A. Yes.

Q. How would one do that?

A. The mechanism by which you assure fetal demise is an intracardiac injection of either potassium chloride or digoxin. Potassium chloride is a naturally occurring salt that in high concentrations causes a cardiac arrest or cardiac arrhythmia and fetal death. Digoxin is a chronotropic and inotropic agent derived from foxglove.

THE COURT: What does that all mean, Doctor?

THE WITNESS: The drug?

THE COURT: Yes.

THE WITNESS: Digoxin is a drug which is derived from foxglove.

Q. What is foxglove?

A. Foxglove is a common plant. It is a biennial plant which has been used over a long period of time for the treatment of cardiac failure.

[1150]

Q. Have you ever injected KCl or digoxin into the fetal heart before beginning a pregnancy termination in the second trimester?

A. Yes, I have.

Q. How do you determine which agent you will use, KCl or digoxin?

A. It is usually whatever is available.

Q. So you use them interchangeably?

A. When you are doing the intracardiac procedure, yes.

Q. Can a physician effect fetal demise by injecting KCl or digoxin anywhere other than in the fetal heart?

A. You can't guarantee the process.

Q. Why not?

A. I have been unable in certain cases to actually put a needle into the heart for technical reasons or because the mother is obese or the fetus is in a particularly difficult position to gain access to the heart. When you put these agents not in the heart or near the heart, you can't guarantee fetal death.

Q. Has it ever happened that you have attempted to inject a feticidal agent into the fetal heart but failed to do so and demise failed to occur?

A. Yes.

Q. Can you describe that for us, please.

A. It was a patient that had a particular body ambitus plus a [1151] fetus which was very difficult to visualize ultrasonically, by ultrasound. Technically, we couldn't get the needle into the heart. We chose to put digoxin into the muscle mass of the fetus. The fetus still had a heartbeat the next day.

Q. Do you routinely inject KCl or digoxin into the fetal heart before a second trimester termination?

A. No, I do not.

Q. Do you ever?

A. When we are doing induction procedures, I do, because there is medical benefit. There is a body of information on the use of misoprostol, that misoprostol,

used in the face of a dead fetus, actually facilitates delivery, and the induction interval from the beginning of the use of misoprostol until delivery of the fetus is shorter.

Q. What about in the context of D&E? Do you do intracardiac injections to effect fetal demise prior to D&E's?

A. No.

Q. Why not?

A. There is no medical benefit.

Q. Under what circumstances might you do an intracardiac injection to effect demise before a D&E?

A. If the patient requested it.

Q. Doctor, you have testified about a couple of situations where it would be difficult or impossible to achieve an intracardiac injection, such as an obese patient or positioning [1152] of the fetus. Are there any other situations where it would be either difficult or impossible to achieve an intracardiac injection?

A. When you have loss of amniotic fluid, you don't have an interface between the fetus and the amniotic fluid, you can just be compressed with maternal tissue so that you may not be able to visualize where your needle is going.

Q. Are there maternal health conditions that increase the risk of performing an intracardiac injection?

A. Yes, there are.

Q. What are those?

A. Things that come to mind include infection in the uterus, where you do not a want to put a needle through the abdominal wall into the uterus and then withdraw it, because you increase the risk of infection in the tissues outside the uterus, such as the peritoneal cavity and subcutaneous tissue. Similarly—

Q. Can I interrupt for one second and ask you to tell us what the peritoneal cavity and the sub—you will have to repeat that word.

A. I'm sorry. The peritoneal cavity is the cavity in which the bowel and the uterus and the ovaries sit within the abdomen. The subcutaneous tissue is the tissue below the skin and above the muscle. The layer that holds this together is called the fascia.

Q. You have said that you wouldn't want to attempt this sort [1153] of injection into the maternal abdomen because it might seed the woman's abdominal cavity and the area below the skin, that is correct?

A. Yes.

Q. I interrupted you. Can you go on and explain the other risks of doing such an injection.

A. The other situation is that with a prior surgical incision into the abdomen, the patient may have scar tissue in the peritoneal cavity or bowel between the abdominal wall and the uterus. You certainly don't want to go through the bowel and then go into the uterus. Again, you are perforating other tissues and you are also increasing the chance of infection.

Q. Are there any other situations that would create a risk for attempting an intracardiac fetal injection?

A. If you had a bleeding disorder, such as disseminated intravascular coagulation or low platelet

counts or leukemia, you wouldn't want to subject the mother to an additional procedure where you might get hemorrhage, especially in the subcutaneous tissue or in the peritoneal cavity, where you could get a lot of blood concealed from view and actually be causing a hemorrhage in the mother.

THE COURT: Ms. Chaiten, is this a convenient time to take our morning break?

MS. CHAITEN: That would be fine, your Honor.

THE COURT: The Court will stand in recess.

[1154]

(Recess)

THE COURT: Ms. Chaiten, you may inquire.

MS. CHAITEN: Thank you, your Honor.

Q. Doctor, we were talking about intracardiac injections of KCl and digoxin prior to the break. Is there a risk of injecting the woman with the feticidal agent as you endeavor to inject the fetal heart?

A. If you actually have it within the fetus, there is no risk to the mother. However, if you inadvertently get into maternal circulation, there is a risk to her.

Q. What would that risk entail?

A. It would be cardiac arrhythmias or irregular heartbeat would be the most common.

Q. How did you learn to perform an intracardiac fetal injection?

A. It was an extension of my maternal fetal medicine training.

Q. In what context?

A. We initially started to do intracardiac injections of small fetuses in the end of the first trimester and the beginning of the second for the purpose of reducing multifetal pregnancies or multiple gestations, either with a twin gestation, where one twin is normal and the other is abnormal, or of a situation where we have too many fetuses within the uterus.

Q. To the best of your knowledge, is this a skill that is routinely taught to obstetricians and gynecologists?

[1155]

A. No, it is not.

Q. Doctor, you testified earlier, or yesterday I guess it was, that D&E practice has evolved since you were trained in this area in the mid 1970's, is that correct?

A. Yes.

* * * * *

[1156]

BY MS. CHAITEN:

Q. Can you tell us what you were referring to when you stated that?

A. When I was a resident we did D&Es through 16 and a half weeks, and when I left my residency and was in practice we began to apply serial laminaria to achieve larger amounts of dilatation because laminaria were more readily available and we could thereby terminate fetuses in the second trimester to about 20 weeks.

And, with time, we actually went in further into 23 and five sevenths so that we changed the way we did the procedure so that we could make the procedure safe for the patient. And generally this had to do with

multiple laminaria insertions for the mother prior to doing the procedure.

Moreover, with changes in instrumentation or availability of different instruments we were able to deliver more of the fetuses intact.

Q. Why is that important?

A. That decreases the risk to the mother and decreasing the number of passes of instruments into the uterus, and we can actually get the fetus intact for genetic purposes.

Q. Can you describe for us how this evolution to both doing D&Es later and more intact occurred within the medical community?

A. It was continuation or extension of procedure which I had [1157] trained to do in my residency. And by talking to other physicians and by reading the literature we changed the procedure or adapted the procedure to our own particular surgical circumstances.

At one point we were using dilapan, which is a synthetic laminaria which achieves dilatation over about a four hour period. These are no longer available on the market. We used those at one period of time, then we substituted another process by which we achieved maximal cervical dilatation or the amount necessary to empty the contents of the uterus.

And we had also incorporated misoprostol, either oral or vaginally, at the suggestion of other physicians to help the cervix soften and dilate.

Q. So you have mentioned talking with other physicians, is this at meetings and conferences?

A. Yes.

Q. And then what do you do after you have gone to a meeting or in some other way discussed a procedure with another physician in terms of your attempt to apply it to your own practice?

A. You incorporate the suggestions of other physicians into your practice.

Q. Do you incorporate those suggestions exactly as they do it?

A. Sometimes. Sometimes not.

Sometimes you have a way of doing things that you can come up with, a variation of what they suggested that works [1158] better in your hands.

Q. And then what happens?

A. You adapt a protocol to that particular change in the procedure.

Q. And then do you have any other discussions with other physicians?

A. You can. You then suggest things to other physicians.

Eventually you may have enough experience that you feel that your procedure is better and then you can do a study and publish it showing the changes and the safety and efficacy of that particular variation of procedure.

Q. Is this process by which D&E has evolved since the mid '70s consistent with your understanding of how surgical techniques, generally, evolve?

A. Yes, it is.

Q. Doctor, you testified earlier that you have been a member of the Northwestern University Institutional Review Board, or IRB, for 12 years, is that correct?

A. Yes.

Q. What are your responsibilities as a member of the IRB?

A. On a monthly basis I review protocols that are presented to the institutional review board for approval of a study of a particular, usually scientific hypothesis, and we look at the study protocol as to whether or not it can answer the question raised, whether it is ethical; and then the consent process and [1159] the training and the conduct of that research by the particular investigators.

Q. In what circumstances is IRB approval required?

A. For any study involving human research.

Q. Is IRB approval required for changes in patient care by an individual physician?

A. If it's in the context of a study, yes.

Q. What if it is not in the context of a study?

A. Then it does not require institutional review board approval.

Q. Before a physician varies a surgical technique or approach, does the physician need IRB approval?

A. No.

Q. In your experience, have physicians sought IRB approval for new surgical techniques prior to performing them on patients?

A. Only in the context of a study.

Q. Dr. Frederiksen, you have got your black binder in front of you and if you would, please turn to Tab 69, which is Plaintiff's Exhibit 69. This is a copy of the Partial-Birth Abortion Ban Act of 2003.

Could you please turn to Section 14C under the findings that appears at page S-34? I would like to direct your attention to the first sentence.

Doctor, assuming that we are talking about an intact approach to D&E, do you agree that intact D&E has "never been [1160] subject to even a minimal amount of the normal medical practice development"?

A. I disagree.

Q. Do you have an opinion as to whether a ban on intact D&E would affect the advancement of abortion practice?

A. Yes.

Q. What is that opinion?

A. It would stop the ability to explore the advantages of intact D&E to the patient.

Q. Now, would you please—

THE COURT: Could I have that answer read again, please?

(Record read)

BY MS. CHAITEN:

Q. Doctor, if you would now look at paragraph 14B on that same page, I direct your attention to the last sentence of that paragraph which reads:

"Indeed, unlike more commonly used abortion procedures there are currently no medical schools that provide instructions on abortions that include the

instruction in"—and again assuming we are talking about intact D&E—"that include instruction in intact D&E in their curriculum."

Do you agree with this statement?

A. No, I do not.

Q. Why not?

[1161]

A. We have been teaching intact or delivery of an intact fetus as possible at our medical school for the last several years.

THE COURT: How many, Doctor?

THE WITNESS: I really can't tell you. I don't remember.

THE COURT: You are teaching there, aren't you?

THE WITNESS: Yes, but I've taught there for over 20 years and I don't remember exactly when we got to the point where we were basically doing as intact a procedure as possible. That's been the general way we have made D&Es safer over this period of time.

When we incorporated it into teaching I can't tell you.

THE COURT: Can you give us an approximation, Doctor?

THE WITNESS: Probably over the last 10 years.

BY MS. CHAITEN:

Q. Doctor, do you have an opinion as to whether a ban on intact D&E would have an impact on abortion education?

A. It would essentially not allow certain aspects of abortion training to be trained, to be taught.

Q. Dr. Frederiksen, is intact D&E the only technique available to terminate pregnancy in the second trimester?

A. It is not necessarily the only technique but it is the safest.

MS. CHAITEN: Thank you, Doctor. I have no further

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[Dr. Marilynn Frederiksen—Cross]

[1174]

A. Currently I do not.

Q. Doctor, isn't it true that between 20 and 24 weeks the risks of D&E and medical induction are similar?

A. They may be, yes.

Q. Well, Doctor, your colleague, Dr. Hammond, testified at this trial that the risks of D&E and medical induction are similar between 20 and 24 weeks, is that testimony wrong?

A. No.

Q. And, Dr. Stubblefield, was he wrong when he wrote in his chapter, gynecological—his chapter in the book gynecologic and obstetric and related surgery, his chapter on first and second trimester abortion that, "labor induction method and D&E are comparable in the later mid-trimester"?

MS. CHAITEN: Objection, lack of foundation.

THE COURT: What is foundation?

MS. CHAITEN: And hearsay. Sorry.

THE COURT: Overruled.

THE WITNESS: I'm unfamiliar with Dr. Stubblefield's statement and I don't know what textbook you are referring to.

THE COURT: Show the witness this textbook, if you wish.

MS. WOLSTEIN: Thank you, your Honor.

THE COURT: Are you familiar with Dr. Stubblefield's name?

THE WITNESS: Yes, yes.

* * * * *

[1177] bring about fetal demise in a second trimester abortion was not accurate, was it?

A. I don't routinely do it.

Q. Well, Doctor, your protocol for performing induction abortions includes an intracardiac injection of potassium chloride the day before doing the induction, doesn't it?

A. Yes; but it doesn't include an intracardiac injection prior to a D&E.

Q. Well, you testified on your direct, Doctor, that you don't routinely do intracardiac injections before second trimester abortions.

A. I don't routinely do intracardiac injections before D&E procedures but I do with inductions.

Q. And you routinely do intracardiac injection with your induction protocol, right?

A. Routinely, yes.

Q. And these days you use potassium chloride rather than digoxin, right?

A. Yes.

Q. And the potassium chloride injection is an ultrasound guided procedure that assures the death of the fetus, right?

A. Yes.

Q. And a degree of risk associated with a potassium chloride injection is analogous to the degree of risk a sociated with amniocentesis? Would you agree with that?

* * * * *

[1221]

A. That is correct.

Q. That means you cannot confirm a brain defect with an intact D&E, right?

A. Yes.

Q. A defect of the brain cannot be confirmed by any means other than an induction abortion, isn't that so?

A. Yes.

Q. So you cannot confirm a diagnosis of hydrocephalus with a fetus in which the brain contents have been suctioned by a D&E, correct?

A. That's correct.

Q. If you are dealing with a hydrocephalic fetus where you need a diagnosis, it is best to do an induction, right?

A. Yes.

Q. Doctor, you use the term "intact dilatation and evacuation" synonymously with "intact dilatation and extraction," don't you?

A. Could you repeat the question, please.

THE COURT: Mr. Reporter.

(Question read)

A. Yes.

Q. You have also referred to intact D&E as a "breech extraction variant of D&E," right?

A. Yes.

Q. An intact D&E can also be referred to as "dilation and [1222] extraction" or "D&X," right?

A. Yes.

Q. D&X was developed for late second trimester abortions, wasn't it?

A. Yes.

Q. D&X is especially suited to late second trimester abortions?

A. Yes.

Q. One reason D&X is especially suited to late second trimester abortions is because dismemberment of the fetus becomes more difficult beyond 22 or 23 weeks gestation, right?

A. Yes.

Q. Fetal tissue becomes more difficult to break apart somewhere between 22 and 23 weeks?

A. Yes.

Q. In fact, you yourself usually do the D&X procedure beyond 20 weeks, right?

A. Yes.

Q. When you do the surgical portion of the D&E procedure, you place a Grave's speculum in the vagina?

A. Yes.

Q. Then the cervix is prepped with Betadine and lidocaine is infused in the anterior lip of the cervix?

A. Yes.

Q. Then the cervix is grasped either with one tenaculum or two * * *.

* * * * *

[1225] the back of the skull and reducing the head with a scissors, right?

A. Yes.

Q. To disrupt the fetal brain, you use your finger, and that compresses the contents of the head and allows it to pass through the cervix?

A. Yes.

Q. When you do a D&X in breech presentation, you grasp the fetal foot, and with careful manipulation of the fetus you deliver the fetus to the trunk, right?

A. Yes.

Q. Then you essentially do a breech delivery, where you are left with the fetal head inside the cervix, right?

A. Yes.

Q. Then you either compress the head or you enter the skull with scissors and disrupt the fetal brain, correct?

A. Correct.

Q. In your view, Doctor, D&X does not necessarily involve converting the fetus to a breech presentation, does it?

A. Correct.

Q. If the fetus is in head-first presentation and if you take certain other steps, you still could be doing a D&X, right?

A. Correct.

Q. You have done the D&X when the fetus was in head-first presentation without converting it to a breech, right?

* * * * *

[Dr. Marilynn Frederiksen—Redirect]

[1236] it is it can accidentally get into the maternal circulation.

That type of injection into the amniotic cavity occurred with saline and with prostaglandins when we were doing more installation abortion techniques in the—a while ago.

Q. So, when you do an amniocentesis though, you're not at risk for injecting the pregnant woman with the toxic substance?

A. No.

Q. Dr. Frederiksen, are there some maternal health conditions where you would be unwilling to perform an intracardiac injection even if a patient requested it?

A. Yes.

Q. And what would those—and some examples of those situations be?

A. Well, if there was going to be a risk to the mother, such as if there was overlying bowel from prior surgical procedures, if there was a bleeding abnormality in the mother, if there was intrauterine infection such as chorioamnionitis, or if there was a chance that the mother who had an increased incidence of sepsis and the uterus was infected, by putting another needle into the uterus you could inadvertently seed maternal tissues.

Q. Doctor, you were asked a number of questions about amniocentesis on cross, I am just going back to amniocentesis for a minute.

Would you do an amniocentesis on a woman who was suffering from sepsis?

[1237]

A. No.

Q. Why not?

A. Because you would be putting a needle into an infected area and then withdrawing it through the maternal tissues.

Q. And what would your concerns about that be?

A. Again, infecting maternal tissues.

MS. CHAITEN: I have no more questions at this time.

THE COURT: I suppose, Ms. Wolstein, do you have some recross?

MS. WOLSTEIN: No, your Honor. Nothing further.

THE COURT: All right, Doctor. You may step down. Why don't we take our afternoon recess then at this time.

(Recess)

THE COURT: Please, be seated. Just one or two things before we continue with testimony.

With regard to the deposition testimony of the two doctors, I would ask that you get copies of the transcripts to my chambers this afternoon along with, from the government, any objections or counter-designations. But that we need the transcripts to review it and try to be prepared to make any rulings, if we need make any, by tomorrow.

With regard to the question of whatever Judge Hamilton is doing on the west coast with regard to Dr. Bowes and Dr. Sprang, that I would hope that you are coordinating * * *

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